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No. 96-____

IN THE

Supreme Court of the United States

OCTOBER TERM, 1996

BIO-TECHNOLOGY GENERAL CORP.
and BIO-TECHNOLOGY GENERAL (ISRAEL), LTD.,

Petitioners,

—v.—

GENENTECH, INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether the "materially changed" provision of the process patent amendment to the Patent Law, 35 U.S.C. § 271(g), is to be interpreted by legislative history, contrary to the explicit language of the statute, to bar importation of a product made by a process practiced abroad, although the product clearly has been materially changed before importation?

2. Whether the "substantial preparation" necessary to invoke the "grandfather clause" exception to the process patent amendment to the Patent Law, 35 U.S.C. § 271(g), requires such activity as the building of a plant in the United States, although the statutory exception is directed to excluding process patent infringement by foreign manufacturers which commenced activity prior to the effective date of the statute and the manufacturer had made its investment in good faith reliance upon existing law?

3. Whether a patent owner is barred by the doctrines of (a) claim preclusion or (b) unclean hands from seeking injunctive relief in a district court against a foreign manufacturer after being denied the same relief as a sanction imposed by the International Trade Commission, thereby depriving the manufacturer of due process of law?

PARTIES

The parties named in the caption are the only parties to the proceeding in the Court of Appeals. However, the action in the District Court has been consolidated with three other civil actions. Parties to those actions, other than the parties here, are Novo Nordisk of North America, Inc., Novo Nordisk Pharmaceuticals, Inc., and Novo Nordisk A/S.

Pursuant to Supreme Court Rule 29.1, petitioners Bio-Technology General Corp. ("BTG") and Bio-Technology General (Israel), Ltd. ("BTG Israel") state that BTG is the parent company of BTG Israel. Neither petitioner has any other parent or subsidiary companies.

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Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

Petitioners Bio-Technology General Corp. and Bio-Technology General (Israel), Ltd. respectfully pray that a writ of certiorari issue to review the Judgment and Opinion of the United States Court of Appeals for the Federal Circuit, dated April 8, 1996.

I. OPINIONS BELOW

The opinion of the United States Court of Appeals for the Federal Circuit is now reported at 80 F.3d 1553 and appears at pp. 1a-21a of the appendix to this Petition.[1]

[1] All references herein (to "__a") refer to Petitioner's Appendix (numbered pages 1a-127a), submitted concurrently herewith.

The Order of Preliminary Injunction of the United States District Court for the Southern District of New York, which was affirmed on appeal, is not reported and appears at pages 22a to 23a of the appendix to this Petition.

The Findings of Fact and Conclusions of Law of the United States District Court for the Southern District of New York in Support of the Order of Preliminary Injunction, is not reported and appears at pages 24a-73a of the appendix to this Petition.[2]

The Order of the Court of Appeals for the Federal Circuit denying Petitioners' petition for rehearing and suggestion for rehearing *en banc* is not reported and appears at pages 74a-75a of the appendix to this Petition.

The relevant portion of the Initial Determination of the Administrative Law Judge ("ALJ") of the International Trade Commission is not reported and appears at pages 76a to 123a of the appendix to this Petition[3].

The Final Determination of the International Trade Commission, determining not to review an Administrative Law Judge's Initial Determination that Genentech's Complaint against BTG should be dismissed with prejudice as a sanction for withholding material documents during an investigation, is not reported and appears at pages 124a to 127a of the appendix to this Petition.

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[2] The Findings of Fact and Conclusions of Law of the District Court were filed under seal, as they contain confidential information. A public version also was issued, from which confidential information was redacted. The public version appears at pages 24a-73a of the appendix to this Petition, and omitted confidential information is indicated by "[ ]". The confidential version has not been submitted herewith, as the confidential information is not relevant to this Petition.

[3] The entire Initial Determination, which is more than 500 pages long, contains findings which were not adopted by the ITC and which are not relevant to this petition. Those findings have been redacted.

II. JURISDICTION

The judgment of the United States Court of Appeals for the Federal Circuit was filed on April 8, 1996. A Petition for Rehearing was denied on May 20, 1996. The jurisdiction of this Court is invoked pursuant to Title 28, U.S.C. § 1254(1).

III. STATUTES INVOLVED

The statute involved in this Petition is § 271(g) of the Patent Law, 35 U.S.C. § 271(g), which provides in full as follows:

> (g) Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the non-commercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after-
>
> (1) it is materially changed by subsequent processes; or
>
> (2) it becomes a trivial and nonessential component of another product.

The implementing legislation of 35 U.S.C. § 271(g), found at Section 9006 of Public Law 100-418, also is involved in this appeal and provides in part as follows:

> (a) In general.—The amendments made by this subtitle . . . take effect 6 months after the date of enactment of

this Act [Aug. 23, 1988] and, subject to subsections (b) and (c), shall apply only with respect to products made or imported after the effective date of the amendments made by this subtitle.

(b) Exceptions.—The amendments made by this subtitle shall not abridge or affect the right of any person or any successor in business of such person to continue to use, sell, or import any specific product already in substantial and continuous sale or use by such person in the United States on January 1, 1988, or for which substantial preparation by such person for such sale or use was made before such date, to the extent equitable for the protection of commercial investments made or business commenced in the United States before such date. . . (*See* 35 U.S.C.A. § 271 (West Supp. 1996) at p. 60).

IV. STATEMENT OF THE CASE

The United States District Court for the Southern District of New York had jurisdiction over this action, a declaratory judgment action brought by BTG, under the Patent Laws of the United States, Title 35, United States Code, pursuant to 28 U.S.C. § 1338(a) and §§ 2201-2202.

BTG, an American company, makes and sells a variety of pharmaceutical products, including human growth hormone. For more than a decade, BTG made enormous investments in the research, development and commercialization of human growth hormone. All told, BTG spent over $20,000,000 over the years to bring its human growth hormone product to market, including construction of a manufacturing plant in Israel to make human growth hormone. The plant was substantially completed by January 1, 1988. The funds to build the plant were raised from investors in the United States. Indeed, BTG raised more than $40,000,000 from American investors from 1983 through 1987. BTG's New Drug Application ("NDA") for human growth hormone for treating growth hormone defi-

ciency in children was approved by the Food and Drug Administration ("FDA") on May 25, 1995.

BTG's BIO-TROPIN human growth hormone is manufactured in Israel by BTG-Israel, BTG's subsidiary. BTG intended to import into the United States human growth hormone made by BTG-Israel. However, BTG has never been able to do so because of the District Court's Order granting a preliminary injunction. BTG never imported and never intended to import into the United States plasmids or replicable cloning vehicles made by BTG-Israel which are used in the process for making human growth hormone. The production plasmid used by BTG for making human growth hormone was made by BTG-Israel in 1983 and has never been made again. BTG's process results in the formation of inclusion bodies from which human growth hormone can be obtained only by material changes using methods patented by BTG. BTG never has imported and never intended to import these inclusion bodies, which have no value in and of themselves.[4]

Genentech makes and sells two growth hormone products. Its original product, PROTROPIN, is methionyl human growth hormone. Its newer product, NUTROPIN, is human growth hormone.

This case is an outgrowth from an investigation of BTG's alleged importation of human growth hormone conducted by the International Trade Commission, entitled *In re Certain Recombinantly Produced Human Growth Hormones*, Inv. No. 337-TA-358. Genentech had instituted the investigation by claiming infringement of U.S. Patents Nos. 4,342,832; 4,601,980; and 5,221,619.

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[4] The making of a plasmid or replicable cloning vehicle is the process claimed in Genentech's U.S. Patent No. 4,342,832. The making of human growth hormone involving isolation and purification of "expressed human growth hormone" is the process claimed in Genentech's U.S. Patent No. 4,601,980.

On November 30, 1994, the ALJ made an Initial Determination that Genentech's complaint against BTG should be dismissed with prejudice as a sanction for Genentech's misconduct in withholding material documents during the proceeding. The ALJ found that there had been no violation by BTG of 19 U.S.C. § 1337. Further, the ALJ found that Genentech's withholding of documents had "violated irreparably the due process rights of" BTG (95a). The ALJ's Initial Determination of dismissal was affirmed by a Final Determination of the Commission on January 17, 1995. Genentech appealed the ITC's Final Determination to the Court of Appeals for the Federal Circuit, Appeal No. 95-1244. The appeal was heard concurrently with the hearing of this appeal but has not yet been decided.

Immediately after the ALJ's initial determination, Genentech sued BTG for patent infringement in the District of Delaware on December 1, 1994. On January 6, 1995, BTG filed an action in the Southern District of New York, seeking a declaratory judgment of invalidity and non-infringement of the same two Genentech patents, Nos. 4,342,832 and 4,601,980[5]. Genentech counterclaimed for infringement of those patents. The Delaware case eventually was transferred to New York and consolidated with the New York case.

On May 30, 1995, immediately after BTG obtained its FDA approval, Genentech sought a temporary restraining order and a preliminary injunction. The District Court denied the TRO since BTG was not yet in a position to market the product in the United States. However, the Court held a hearing on the preliminary injunction motion.

BTG moved to dismiss Genentech's infringement counterclaim on the ground that the ITC's Final Determination dismissing Genentech's complaint against BTG with prejudice as a sanction for Genentech's misconduct was *res judicata* and

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[5] The complaint and counterclaim also concern Patent No. 5,221,619, but that patent was not the subject of the preliminary injunction motion and order. Only claim 1 of the '832 patent and claim 2 of the '980 patent were at issue before the District Court and Court of Appeals.

claim preclusive. The District Court never decided the motion, but refused to consider Genentech's misconduct before the ITC as evidence in support of BTG's unclean hands defense.

On August 10, 1995, District Judge Motley entered a Preliminary Injunction Order precluding BTG and BTG Israel from making, importing, distributing, offering for sale and selling human growth hormone in this country.[6]

BTG and BTG Israel appealed the District Court's Preliminary Injunction Order. On April 8, 1996, the Court of Appeals for the Federal Circuit entered its Opinion and Judgment affirming the District Court's Order.

BTG and BTG Israel then sought rehearing on the grounds that the Federal Circuit panel had, *inter alia*, improperly determined two issues of first impression relating to Section 271(g) of the Patent Law, 35 U.S.C. § 271(g), and had misapplied existing law with regard to deference to be given determinations by the ITC. On May 20, 1996, the petition for rehearing and a suggestion for rehearing *en banc* were denied (74a-75a).

As explained below, the Federal Circuit improperly determined two questions of first impression under Section 271(g) of the Patent Law, misapplied existing law in direct conflict with its own opinions and decided additional questions of claim preclusion and unclean hands in conflict with opinions of other Courts of Appeal.

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[6] The District Court adopted wholesale the proposed findings of Genentech. *See, Anderson v. City of Bessemer City*, 470 U.S. 564, 572-573 (1985) (criticizing that procedure).

V. ARGUMENT—REASONS FOR GRANTING THE WRIT

A. The Court Of Appeals Has Decided An Important Question Of Federal Law Respecting The "Material Change" Provision of 35 U.S.C. § 271(g) Which Has Not Been, But Should Be, Settled By This Court.

Congress enacted a process patent amendment to the Patent Law, 35 U.S.C. § 271(g), in 1988, to prevent the use of a patented process outside the United States to make and import products for sale and use in this country. That provision exempts from patent infringement the use of a process abroad for making a product imported into the United States, if the product of the process is "materially changed" by subsequent processes. This Court has not previously determined the meaning of "materially changed".

Genentech's Patent No. 4,342,832 is directed only to a method of making a plasmid, which might be used in a process of making human growth hormone. The Court of Appeals held that the human growth hormone which BTG expected to import is materially changed from the plasmid. The Court said:

> There is little doubt that the plasmid product of the claimed process and hGH are entirely different materials, one being more than materially changed in relation to the other. hGH is not a mere modification of the plasmid. (12a).

There is no doubt that BTG never imported any plasmid into the United States. Indeed, neither BTG nor BTG Israel ever made the plasmid after 1983. Accordingly, there could have been no violation of Section 271(g).

In this matter of first impression, the Court of Appeals, despite the clear language of the statute, relied on legislative history to establish that Section 271(g) must be interpreted to prevent the importation of BTG's human growth hormone as not "materially changed" (12a). However, a court cannot look

to legislative history to rewrite a clear statutory provision. *Norfolk & Western Ry. Co. v. American Train Dispatchers Ass'n.*, 111 S.Ct. 1156, 1163 (1991).

Even if the legislative history relied upon by the Court of Appeals provides a useful interpretive guide, that history notes that a product resulting from expression from a bacterium containing a plasmid is an infringement only "if it would not have been possible or commercially viable to make the different organism and product expressed therefrom but for the patented process". S. Rep. No. 83, 100th Cong., 1st Sess. 51 (1987).

In that connection, on February 26, 1996, the same panel of the Court of Appeals decided the appeal in *Novo Nordisk of North America, Inc. v. Genentech, Inc.*, 77 F.3d 1364 (Fed. Cir. 1996). The panel held that Novo Nordisk used a different, non-infringing process for making its human growth hormone. Thus, the Court of Appeals clearly overlooked the fact that it is both commercially viable and possible to make human growth hormone without infringing Genentech's patented process. There is no factual or legal basis for concluding that BTG's human growth hormone could be made only by Genentech's patented process. The Court of Appeals' interpretation of "materially changed", relying upon ambiguous legislative history to find infringement, was erroneous.

Just as important, the Federal Circuit itself reached a different result in *Eli Lilly & Co. v. American Cyanamid Co.*, 82 F.3d 1568 (Fed. Cir. 1996), decided after this case. There, a different panel of that Court concluded that the legislative history provides no "conclusive answer". *Id.* at 1578. Indeed, the Court held there that since there was a non-infringing, commercially viable alternative to the patented process alleged to be infringed in that case, the "materially changed" language of Section 271(g) could not be interpreted to cover a product which was different than the product ultimately imported, even though the alleged infringer did not use that alternative process. *Id.* at 1577.

Since the Court of Appeals' *interpretation* in this case remains in effect, the meaning of the term "materially changed" continues to be uncertain. This important issue of statutory interpretation, which has arisen in three cases this year alone, should be settled by this Court.

B. The Court Of Appeals Has Decided An Important Question Of Federal Law Respecting The "Grandfather Clause" Exception To 35 U.S.C. § 271(g) Which Has Not Been, But Should Be, Settled By This Court.

In 1988, when Congress enacted the process patent amendment to the Patent Law, 35 U.S.C. § 271(g), it exempted from the operation of the process patent amendment those who had made "substantial preparation" for sale or use in this country prior to January 1, 1988. Public Law 100-418, § 9006(b), 102 Stat. 1107, 1567 (1988). This Court has not previously interpreted the "substantial preparation" provision of the "grandfather clause."

The Court of Appeals held, in an interpretation of first impression, that the exception may be applicable if substantial preparation was made for such sale or use before January 1, 1988. "Substantial preparation must consist of activities closely associated with the practice of the claimed invention. One must, for example, invest the money to develop a product or build a plant to make the product in order to meet that test." (14a).

There is no dispute that BTG raised in the United States the money to develop its human growth hormone product prior to the critical date (14a). There also is no question that BTG had substantially constructed a plant in Israel prior to the effective date of the process patent amendment.

The Court of Appeals interpreted the "substantial preparation" provision to require that the plant be constructed and all other expenditures be made in the United States. With that interpretation, no foreign-based manufacturer could qualify for the exception. Yet, the only purpose of Section 271(g) was

to extend the United States Patent Law to reach newly established foreign manufacturing processes. Otherwise, carrying out a patented process in the United States always would have been an infringing act under Section 271(a) of the Patent Law, and there would have been no need either for the process patent amendment or for the "grandfather clause" exception. BTG surely had developed a product and commenced business in the United States and was entitled to rely upon the exception as it properly should have been interpreted. BTG has been deprived of the value of its investment entered into in good faith in reliance upon existing law. In essence, the Court of Appeals has made the process patent amendment retroactive to create an infringement situation where one previously had not existed. *See, Kaiser Aluminum & Chemical Corp. v. Bonjorno*, 110 S.Ct. 1570, 1577 (1990) (a statute should not be applied retroactively unless clearly stated).

This issue of statutory interpretation of the Patent Law creates a problem for all manufacturers which have foreign operations. This important issue should be settled by this Court.

C. The Opinion Of The Court Of Appeals In Holding That Genentech Was Not Barred From Injunctive Relief By Claim Preclusion Or Unclean Hands Conflicts With The Opinions Of Other Circuit Courts.

Genentech initially sought to prevent BTG's importation of human growth hormone for sale and use in the United States by filing a petition in the ITC seeking an exclusion order. Genentech chose the forum. However, its application for a temporary exclusion order was denied, and after a full hearing, its complaint seeking a permanent exclusion order was dismissed with prejudice as a sanction for the wrongful withholding of material, non-privileged documents from BTG (and from Novo Nordisk, a co-respondent). No final determination was rendered on the merits by the ITC as to the validity or infringement of the same patents as are in suit here.

1. Claim Preclusion

This Court has held that preclusive effect should be given to the determinations of administrative agencies when an agency is acting in a judicial capacity. *United States v. Utah Contr. & Mining Co.*, 384 U.S. 394, 421-422 (1966).

Thus, the Court of Appeals misapprehended applicable law in holding that, ". . . in view of the jurisdictional limitations on the relief available in the ITC, we hold that the ITC's prior decision cannot have claim preclusive effect in the district court." (18a). No decision of any Court of Appeals previously had gone that far. The furthest the Federal Circuit itself had gone was to hold that patent validity decisions of the ITC have no *res judicata* effect. *See Tandon Corp. v. USITC*, 831 F.2d 1017, 1019 (Fed. Cir. 1987).

The Court of Appeals' legal interpretation creates a clearly inequitable situation and, in effect, violates BTG's right to due process by law. It is an invitation for one to bring a proceeding before an administrative tribunal, attempt to hoodwink that tribunal by withholding evidence and then, if unsuccessful, thumb one's nose at the tribunal by bringing a separate action in a district court. That is precisely what Genentech did here.

The Court of Appeals justified Genentech's behavior by distinguishing between the types of relief available from the ITC and from a district court. However, the actual relief sought in both forums essentially was the same. Genentech sought and was refused both a temporary and a permanent exclusion order in the ITC. Genentech sought and was granted a preliminary injunction by the district court. There was no damage claim before either tribunal, since BTG never has imported human growth hormone for sale to the public in the United States. As stated in a case cited by the Court of Appeals, "It is well established that a party may not split a cause of action into separate grounds of recovery and raise the separate grounds in successive lawsuits. . ." *Mars, Inc. v. Nippon Conlux K.K.*, 58 F.3d 616, 619 (Fed. Cir. 1995) (affirming holding of claim preclusion).

The Court of Appeals' decision is contrary to decisions of other appellate courts. In *Union Mfg. Co., Inc. v. Han Baek Trading Co., Ltd.*, 763 F.2d 42, 45 (2d Cir. 1985), the Second Circuit gave preclusive effect to an ITC ruling in an action under Section 43(a) of the Lanham Act. In *Aunyx Corp. v. Canon U.S.A., Inc.*, 978 F.2d 3 (1st Cir. 1992), *cert. denied*, 113 S.Ct. 1416 (1993), the First Circuit gave preclusive effect to an ITC judgment in a Sherman Act case. The Court of Appeals' decision here did not mention either case. The decision creates a conflict among the circuits which should be settled by this Court.

2. Unclean Hands

In addition, the Court of Appeals should have considered Genentech's misconduct before the ITC in the context of BTG's unclean hands defense. It long has been established that unclean hands bars the granting of equitable relief in a patent infringement action. *Precision Inst. Mfg. Co. v. Automotive Maintenance Mach. Co.*, 324 U.S. 806, 814 (1945); *Keystone Driller Co. v. General Excavation Co.*, 290 U.S. 240, 245 (1933). The Court of Appeals misapprehended the law when it held that the unclean hands defense does not apply since the "misconduct did not occur in the context of the present lawsuit" (20a).[7] The misconduct need only involve the same right, as stated in the case cited by the Court, *Warner Bros., Inc. v. Gay Toys, Inc.*, 724 F.2d 327, 334 (2d Cir. 1983). Here, the same patent rights were before both the ITC and the lower courts. BTG was entitled to raise its unclean hands defense as a matter of due process of law. Whether a finding of unclean hands before the ITC precludes the grant of a preliminary injunction by a district court in an action involving the same rights is an important legal issue as to which the circuits now are in conflict and which should be settled by this Court.

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[7] The same panel presently has under consideration Genentech's appeal from the ITC's decision, *Genentech, Inc. v. USITC*, No. 95-1244.

VI. CONCLUSION

For the forgoing reasons, Petitioners respectfully request that this Court grant the Writ of Certiorari.

Dated: August 19, 1996

Respectfully submitted,

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APPENDIX

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

No. 95-1471

DECIDED: April 8, 1996

BIO-TECHNOLOGY GENERAL CORP.
and BIO-TECHNOLOGY GENERAL (ISRAEL), LTD.,

Plaintiffs-Appellants,

—v.—

GENENTECH, INC.,

Defendant-Appellee.

Before ARCHER, *Chief Judge,*
RICH, and LOURIE, *Circuit Judges.*

LOURIE, *Circuit Judge.*

Bio-Technology General Corp. and Bio-Technology General (Israel), Ltd. (collectively "BTG") appeal from the decision of the United States District Court for the Southern District of New York granting a preliminary injunction in favor of Genentech, Inc. *Bio-Technology Gen. Corp. v. Genentech, Inc.*, No. 95 Civ. 0110 (CBM) (S.D.N.Y. Aug. 10,

1995) (preliminary injunction order). Because the court did not abuse its discretion in granting a preliminary injunction, we affirm.

BACKGROUND

Human growth hormone ("hGH") is a 191-amino acid polypeptide hormone secreted by the anterior pituitary gland. It has important metabolic effects, including stimulation of protein synthesis and cellular uptake of amino acids. Genentech is the assignee of two patents relating to hGH that are at issue in this lawsuit. The first patent, U.S. Patent 4,601,980, is directed to a recombinant DNA method for producing a 191- or 192-amino acid human growth hormone product that is identical, or essentially identical, and functionally equivalent to the natural hormone.[1] The product is useful in treating hypopituitary dwarfism in children.

Prior to the '980 invention, hGH could be obtained for therapeutic use only by extracting it from the pituitary glands of human cadavers. Known recombinant DNA methods for producing hGH were deficient; they yielded not only the amino acid sequence of the protein, but also a "leader sequence" of additional amino acids at the beginning of the protein. In the natural synthesis of hGH, the leader sequence enables the protein to emerge from a pituitary cell after expression; the leader is then enzymatically removed. When the product is recombinantly expressed in a bacterial host, however, the leader is not removed and it renders the resulting product biologically inactive.

The invention claimed in the '980 patent solved this problem by providing a method for directly expressing a human growth hormone expression product without a leader

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[1] For discussions of recombinant DNA technology, see *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991); *In re O'Farrell*, 853 F.2d 894, 895-99, 7 USPQ2d 1673, 1674-77 (Fed. Cir. 1988). The '980 patent is also discussed in *Novo Nordisk of North America, Inc. v. Genentech, Inc.*, No. 95-1424 (Fed. Cir. Feb. 26, 1996).

sequence. The inventors started with complementary DNA ("cDNA") encoding hGH and its leader sequence, and cleaved the cDNA encoding the leader sequence along with a portion of the codons encoding hGH to obtain a cDNA fragment containing hGH codons 24-191. Next, they synthesized a DNA fragment corresponding to the 23 missing codons plus a "start" codon, and fused that DNA fragment to the cDNA fragment. They inserted the resulting *semi-synthetic gene* into bacterial cells, which directly expressed a 192-amino acid product, met-hGH, consisting of the hGH molecule and one additional amino acid, methionine ("met"), coded for by the start codon.[2] Met-hGH has essentially the same biological activity as the natural hormone, hGH. The '980 patent teaches that the amino acid, methionine, may be cleaved intracellularly in the bacterial host to produce a product that is identical to the natural hormone. Genentech sells met-hGH and hGH under the trademarks Protropin® and Humatrope®, respectively.

The second patent in suit, U.S. Patent 4,342,832, also assigned to Genentech, contains essentially the same disclosure as the '980 patent.[3] The '832 patent claims, however, are directed to a method for constructing a replicable cloning vehicle (*e.g.*, a plasmid) capable, in a microbial organism, of expressing a particular polypeptide (*e.g.*, human growth hormone).

Like Genentech, BTG manufactures hGH by recombinant DNA techniques using a plasmid that contains a semi-synthetic gene engineered to express hGH without a leader sequence. BTG incorporates the plasmid into bacteria, which then express insoluble met-hGH in the form of biologically-inactive inclusion bodies. In a final step, BTG carries out a purification process that involves recovering soluble met-hGH free of inclusion bodies and cleaving the extra methionine

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[2] In this opinion, we refer to this 192-amino acid expression product as "met-hGH." We use the term "hGH" to refer to either natural human growth hormone or the identical 191-amino acid expression product.

[3] The '980 patent is a division of the '832 patent.

residue to produce the Final product, biologically-active hGH. BTG manufactures hGH in Israel, and it plans to import the product for sale in the United States under the trademark Bio-Tropin®.

BTG filed an Investigational New Drug Application ("IND") for hGH with the Food and Drug Administration ("FDA") in 1985. In 1986, BTG granted American Critical Care ("ACC") an exclusive license under BTG's patents and technology to use and sell hGH in the United States. ACC agreed to make payments to BTG, purchase hGH from BTG, and conduct clinical studies to obtain FDA approval for the product. In 1986, E.I. du Pont de Nemours & Co. ("DuPont") purchased ACC and subsequently became the assignee of the ACC-BTG agreement. During 1986-1987, DuPont paid for and completed human clinical studies directed to the use of hGH to treat growth hormone deficiency in children. In September 1987, DuPont filed a New Drug Application ("NDA") for BTG's hGH product. In 1991 and 1992, BTG reacquired certain rights to the NDA from DuPont. The FDA approved the NDA in May 1995.

In January 1995, BTG sued Genentech in district court, seeking a declaratory judgment that the '980 and '832 patents are invalid, unenforceable, and not infringed by BTG. Genentech counterclaimed for infringement and moved for a preliminary injunction, arguing that BTG's importation of hGH into the United States would infringe the '980 and '832 patents. After a hearing, the district court found that Genentech had established a reasonable likelihood of success on the merits of its counterclaim, since BTG's process for producing hGH was within the literal scope of claim 2 of the '980 patent, BTG's process for making a plasmid was within the literal scope of claim 1 of the '832 patent, and BTG's asserted infringement defenses lacked merit. The court also found that Genentech would suffer irreparable harm absent a preliminary injunction and that the balance of the hardships and the public interest favored the grant of an injunction. The court therefore entered a preliminary injunction against BTG. This

appeal followed. We have jurisdiction pursuant to 28 U.S.C. § 1292(c) (1994).

DISCUSSION

The grant or denial of a preliminary injunction pursuant to 35 U.S.C. § 283 is within the discretion of the district court. *We Care, Inc. v. Ultra-Mark Int'l Corp.*, 930 F.2d 1567, 1570, 18 USPQ2d 1562, 1564 (Fed. Cir. 1991). Accordingly, a court's decision granting a preliminary injunction will be overturned on appeal only upon a showing that the court abused its discretion. *Joy Technologies, Inc. v. Flakt, Inc.*, 6 F.3d 770, 772, 28 USPQ2d 1378, 1380 (Fed. Cir. 1993). An abuse of discretion may be established by showing that the court made a clear error of judgment in weighing the relevant factors or exercised its discretion based upon an error of law or clearly erroneous factual findings. *Id.*

As the moving party, Genentech had to establish a right to a preliminary injunction in light of four factors: (1) a reasonable likelihood of success on the merits; (2) irreparable harm if the injunction were not granted; (3) the balance of hardships tipping in its favor; and (4) the impact of the injunction on the public interest. *We Care, Inc.*, 930 F.2d at 1570, 18 USPQ2d at 1564; *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451, 7 USPQ2d 1191, 1195 (Fed. Cir. 1988); *Nutrition 21 v. United States*, 930 F.2d 867, 869, 18 USPQ2d 1347, 1349 (Fed. Cir. 1991) ("[A]t the preliminary injunction stage, because of the extraordinary nature of the relief, the *patentee* carries the burden of showing likelihood of success on the merits with respect to the patent's validity, enforceability, and infringement."). If Genentech made a "clear showing" that one of the asserted patents is infringed and is not invalid, then it would be entitled to a presumption of irreparable harm. *Atlas Powder Co. v. Ireco Chems.*, 773 F.2d 1230, 1233, 227 USPQ 289, 292 (Fed. Cir. 1985).

A. *Likelihood of Success on the Merits*

The district court found it likely that BTG, by importing hGH into the United States, would infringe Genentech's patent under the Process Patent Amendments Act of 1988 ("PPAA"),[4] since BTG's process for making hGH was within the literal scope of claim 2 of the '980 patent and its process for constructing a replicable cloning vehicle (plasmid) was within the literal scope of claim 1 of the '832 patent. *See* 35 U.S.C.A. § 271(g) (West Supp. 1995). The court rejected BTG's several asserted defenses.

On appeal, BTG raises numerous challenges to the court's determination of likelihood of success. As discussed below, each of these arguments lacks merit.

1. *Infringement of the '980 Patent*

Claim 2 of the '980 patent reads as follows:

> 2. A method for producing human growth hormone which method comprises [1] culturing bacterial transformants containing recombinant plasmids which will, in a transformant bacterium, express a gene for human growth hormone unaccompanied by the leader sequence of human growth hormone or other extraneous protein bound thereto, and [2] isolating and purifying said expressed human growth hormone.

BTG advances three non-infringement arguments with respect to claim 2. First, BTG contends that the product expressed by the bacterial host cells in its process is not "human growth hormone" as specified in claim 2, but rather

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[4] Congress enacted the PPAA as Title IX of the Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, 102 Stat. 1107, 1563 (1988) (codified in scattered sections of 35 U.S.C.). The PPAA made it an act of patent infringement to import, sell, or use in the United States, without authorization, a product made by a process patented in the United States. 35 U.S.C.A. § 271(g) (West Supp. 1995). A provision concerning offers to sell was added to § 271(g) by the Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4809, 4988 (1994) (effective Jan. 1, 1996).

is insoluble met-hGH in the form of biologically-inactive inclusion bodies. This argument is unpersuasive.

The '980 specification defines the expression product produced by the claimed process as follows:

> Of course, the expression product will in every case commence with the amino acid coded for by the translation start signal (in the case of ATG, f-methionine). One can expect this to be removed intracellularly, or in any event to leave the bioactivity of the ultimate product essentially unaffected.

Col. 7, 11. 52-57. The specification therefore teaches that the expression product produced by the claimed process is met-hGH, which may or may not be converted to hGH depending on whether or not the extra methionine residue is cleaved intracellularly in the bacterial host. Thus, met-hGH is an expression product within the scope of the claimed process. *See Novo Nordisk of N. Am., Inc. v. Genentech, Inc.*, No. 95-1424, slip op. at 10 (Fed. Cir. Feb. 26, 1996) ("[W]e construe the claim term 'human growth hormone' [in claim 2 of the '980 patent] to encompass both met-hGH and hGH.").

Furthermore, at the preliminary injunction hearing there was expert testimony that an "inclusion body" is simply an aggregation of protein chains and that insoluble, biologically-inactive met-hGH that form inclusion bodies is still met-hGH. BTG points to no persuasive evidence to the contrary. Moreover, nothing in the claim language, specification, or prosecution history of the '980 patent indicates that the expression product must be biologically active at the time of expression, before it has been isolated and purified. Rather, the district court found that recombinant expression products, whether formed as inclusion bodies or otherwise, are not biologically active until they are isolated from the bacterial host cells and purified. BTG has not shown any error in that conclusion. Thus, that the met-hGH formed during BTG's process is not biologically active is neither surprising nor meaningful; BTG's isolated and purified final product, hGH, is biologically active. We therefore reject BTG's contention that its product is not "human growth hormone."

Second, BTG contends that it uses its own patented purification process to recover soluble, biologically-active hGH from the inclusion bodies of met-hGH and that the '980 patent does not disclose BTG's unique purification process. Thus, BTG argues that its process does not involve "isolating and purifying" a human growth hormone expression product as required by claim 2. We disagree.

Claim 2 uses broad, generic language to define the steps of isolating and purifying the recombinantly produced hGH product. Nothing in the claim language, specification, or prosecution history suggests that the claim is limited to any particular technique for isolating and purifying the product. Further, BTG's process meets these claim limitations. In its NDA, for example, BTG characterized its recovery of soluble, biologically-active hGH from insoluble, biologically-inactive met-hGH in the form of inclusion bodies as a "purification" step. Similarly, at the preliminary injunction hearing there was expert testimony that these processes constitute a "purification" step within the meaning of claim 2. Thus, BTG's process clearly involves "isolating and purifying [the] expressed human growth hormone," as generically defined in claim 2. That BTG patented its unique purification method is irrelevant: "[T]he existence of one's own patent does not constitute a defense to infringement of someone else's patent. It is elementary that a patent grants only the right *to exclude others* and confers no right on its holder to make, use, or sell." *Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A.*, 944 F.2d 870, 879 n.4, 20 USPQ2d 1045, 1052 n.4 (Fed. Cir. 1991).

Third, BTG argues that, assuming its process falls within the literal scope of claim 2, it "materially changes" the product made by the patented process, met-hGH, into hGH before importing the product into the United States. Thus, BTG contends that its importation of hGH into the United States would not be an act of infringement under 35 U.S.C.A. § 271(g).[5] We

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[5] Section 271(g) provides:

Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product

disagree. This argument is based on an assumption that *met-hGH* is the only "product which is made by [the] process patented in the United States" under § 271(g). However, as indicated above, the production of *hGH* must also be considered to be within the literal scope of claim 2. *See Novo Nordisk of N. Am., Inc. v. Genentech, Inc.*, No. 95-1424, slip op. at 10 (Fed. Cir. Feb. 26, 1996).[6] Thus, BTG's imported product (hGH) is within the scope of claim 2. BTG therefore cannot maintain that the "materially changed" exception to infringement applies, because the product made by the patented process is not changed at all, let alone "materially changed." The "materially changed" exception of § 271(g) requires, at a minimum, that there be a real difference between the product imported, offered for sale, sold, or used in the United States and the products produced by the patented process. If claim 2 were limited to a method for producing met-hGH, then we would have to determine whether BTG's conversion of met-hGH to hGH produced a "materially changed" product. But claim 2 is not so limited and thus BTG's argument lacks merit.

We therefore conclude that BTG has not shown that the district court clearly erred in finding that Genentech established a likelihood of success in proving literal infringement of claim 2 of the '980 patent. *See Mannesmann Demag Corp. v. Engineered Metal Prods. Co.*, 793 F.2d 1279, 1282, 230 USPQ 45, 46 (Fed. Cir. 1986) (literal infringement is estab-

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> which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. . . . *A product which is made by a patented process will*, for purposes of this title, *not be considered to be so made after—*
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> (1) *it is materially changed by subsequent processes*; or
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> (2) it becomes a trivial and nonessential component of another product.

35 U.S.C.A. § 271(g) (West Supp. 1995) (emphasis added).

[6] An hGH product could be produced by the claimed process by expressing met-hGH followed by intracellular cleavage of the extra methionine residue in the bacterial host, as taught in the '980 specification, and then isolating and purifying the final product.

lished when every limitation of the patent claim is met in the accused device or process).[7]

2. *Infringement of the '832 Patent*

With respect to claim 1 of the '832 patent, directed to a method of constructing a replicable cloning vehicle (*e.g.*, a plasmid), BTG argues that it does not infringe because it only constructed the plasmid once, in Israel in 1983, before enactment of § 271(g). BTG contends that the district court erred in retroactively applying § 271(g) to conduct that was not an act of infringement when it occurred. We disagree.

Infringement under § 271(g) does not consist of the making of a product by a process patented in the United States; it is the importation, offer to sell, sale, or use of a product made by such process. 35 U.S.C.A. § 271(g) ("Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer."). Liability arises if "the importation, sale, offer to sell, or use of the product occurs during the term of such process patent." *Id.* BTG clearly intends to import and sell hGH in the United States during the term of the '832 patent. This meets the statutory requirement and does not amount to a retroactive imposition of liability.

Furthermore, the PPAA provides that it "shall apply only with respect to products made or imported after the effective date of the amendments made by this subtitle." Process Patent Amendments Act of 1988, Pub. L. No. 100-418, § 9006(a), 102 Stat. 1107, 1567 (1988). Again, because BTG plans to make and import hGH after the effective date of the

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[7] This case is factually distinguishable from *Novo Nordisk of North America, Inc. v. Genentech, Inc.*, No. 95-1424 (Fed. Cir. Feb. 26, 1996). In *Novo*, we held that the district court erred in holding that claim 2 of the '980 patent encompasses a cleavable fusion method for producing human growth hormone. Because Novo's process was a cleavable fusion process, there was no literal infringement and we vacated the court's preliminary injunction. BTG's process, however, does not involve cleavable fusion expression and thus the *Novo* decision does not affect our infringement analysis here.

PPAA (and during the term of the '832 patent), there is no merit to BTG's contention that the district court retroactively imposed liability on BTG.

The more difficult question is whether *hGH* is "a product which is made by a process patented in the United States," even though claim 1 of the '832 patent is directed to a method for producing a replicable cloning vehicle (*e.g.*, a plasmid), not hGH. The statute does not directly answer this question, because it only defines, at least in part, what products "will . . . *not* be considered" to have been "made by" a patented process, namely, those that have been "materially changed by subsequent processes" or that have become "a trivial and nonessential component of another product." 35 U.S.C.A. § 271(g) (emphasis added). The statute does not specify what products will be considered to have been "made by" the patented process, apparently because Congress wanted the courts to resolve this critical question of proximity to the product of the patented process on a case-by-case basis. *See* S. Rep. No. 83, 100th Cong., 1st Sess. 46 (1987) ("Inevitably the courts will have to assess the permutations of this issue of proximity to or distance from the process on a case-by-case basis."); *id.* at 49 ("The Committee expects the courts to exercise careful judgment in distinguishing those products that are too far removed from the patented process, and those that have been changed only in insignificant ways.").

Here, the district court held that hGH is a product that is "made by" the '832 patented process under § 271(g). In so holding, the court relied on the fact that BTG uses the claimed process of making a replicable cloning vehicle as an essential part of an overall process for producing hGH. The court also relied on the legislative history of the PPAA, particularly the Senate Report, which states:

> In the biotechnology field it is well known that naturally occurring organisms contain within them particular genetic sequences composed of unique structural characteristics. The patented process may be for the process of preparing a DNA molecule comprising a specific genetic sequence. A foreign manufacturer uses the

> patented process to prepare the DNA molecule which is the product of the patented process. The foreign manufacturer inserts the DNA molecule into a plasmid or other vector and the plasmid or other vecot [sic, vector] containing the DNA molecule is, inturn [sic], inserted into a host organism; for example, a bacterium. The plasmid-containing host organism still containing the specific genetic sequence undergoes expression to produce the desired polypeptide. Even if a different organism was created by this biotech procedure, if it would not have been possible or commercially viable to make the different organism and product expressed therefrom but for the patented process, the [polypeptide] product will be considered to have been made by the patented process.

S. Rep. No. 83, 100th Cong., 1st Sess. 51 (1987).

There is little doubt that the plasmid product of the claimed process and hGH are entirely different materials, one being more than materially changed in relation to the other. hGH is not a mere modification of the plasmid. However, the above excerpt from the legislative history of the PPAA indicates the correctness of the district court's analysis. The legislative history precisely anticipated this fact situation and indicated Congress's intent that infringement of a process for making a plasmid is not to be avoided by using it to express its intended protein. Moreover, the '832 patent itself explicitly contemplates that the patented process will be used as part of an overall process for producing hGH; indeed, the patent discloses in detail how to make hGH by carrying out the claimed process and other necessary steps. Thus, it cannot be said as a matter of law that the production of hGH is too remote from the claimed process of making a replicable cloning vehicle. We therefore find no error in the court's conclusion that hGH is a product that is "made by" the '832 patented process.

Furthermore, since BTG has not shown that the district court erred in determining that BTG's process for making a plasmid falls within the literal scope of claim 1 of the '832 patent, the district court did not err in finding that Genentech established a likelihood of success in proving literal infringe-

ment of that claim. *See Mannesmann Demag Corp.*, 793 F.2d at 1282, 230 USPQ at 46.[8]

3. *BTG's Defenses*

a. *§ 271(g) - Grandfather Clause*

BTG argues that the "grandfather clause" of the PPAA protects it from liability for infringement under § 271(g). BTG contends that, prior to the effective date of the PPAA, it constructed a plant in Israel for the purpose of manufacturing hGH, filed an IND with the FDA, and licensed ACC (later DuPont) to conduct human clinical studies in the United States. The district court found that these activities did not establish that BTG would likely be entitled to equitable protection under the grandfather clause. We find no error in that conclusion.

In section 9006 of the PPAA, Congress provided an exception to liability under the Act as follows:

> (b) Exceptions.—The amendments made by this subtitle shall not abridge or affect the right of any person or any successor in business of such person to continue to use, sell, or import any specific product already in substantial and continuous sale or use by such person in the United States on January 1, 1988, or for which substantial preparation by such person for such sale or use was made before such date, to the extent equitable for the protection of commercial investments made or business commenced in the United States before such date.

Process Patent Amendments Act of 1988, Pub. L. No. 100-418, § 9006(b), 102 Stat. 1107, 1567 (1988). Thus, for the

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[8] Even assuming, *arguendo*, that the court erred in finding likely literal infringement of the '832 patent, that would not mandate that we vacate the injunction, because the court correctly found a probability of success that BTG literally infringed claim 2 of the '980 patent. Infringement of one valid and enforceable patent claim is all that is required for liability to arise. *E.g.*, *Panduit Corp. v. Dennison Mfg. Co.*, 836 F.2d 1329, 1330 n.1, 5 USPQ2d 1266, 1267 n.1 (Fed. Cir. 1987) ("One is liable for patent infringement if one claim be infringed.").

exception to apply, an accused infringer must establish either (1) that its product was already in substantial and continuous sale or use by the accused infringer in the United States on January 1, 1988, or (2) that it made substantial preparation for such sale or use before January 1, 1988. If either (1) or (2) is established, the accused infringer is entitled to continue to use, sell, or import the product to the extent equitable for the protection of its commercial investments made or business commenced in the United States before that date.

Here, the district court did not err in concluding that BTG did not show entitlement to protection under the "substantial and continuous sale or use" provision, since BTG made only sporadic sales of hGH to DuPont in 1986 and 1987 for human clinical studies. In addition, the court did not err in finding that BTG did not undertake "substantial preparation" to sell or use hGH before 1988, because, while BTG raised substantial sums of money from United States investors before 1988, raising money does not constitute "substantial preparation" under the statute. Substantial preparation must consist of activities closely associated with the practice of the claimed invention. One must, for example, invest the money to develop a product or build a plant to make the product in order to meet that test. Moreover, the funds BTG raised were used to support all of its products under development, not just hGH.

Furthermore, even assuming that BTG's construction of a plant in Israel, its filing of an IND, and its agreement with ACC collectively constituted "substantial preparation" to sell or use hGH, the grandfather clause would only entitle BTG to continue to use, sell, or import the product "to the extent equitable for the protection of commercial investments made or business commenced *in the United States* before [January 1, 1988]." The district court found that most of the money BTG raised was invested outside the United States, not in the United States. The court also found that ACC and DuPont, not BTG, paid for and completed the clinical trials and filed an NDA in the United States, and that BTG did not reacquire rights in the NDA until after 1988. BTG has not shown that

these findings are clearly erroneous. Thus, based on the present record, the district court did not err in holding that BTG is not entitled to equitable relief under the grandfather clause.

b. *Claim Preclusion*

BTG next argues that the district court erred in not giving claim preclusive effect to a decision of the United States International Trade Commission ("ITC"), which dismissed with prejudice Genentech's complaint under 19 U.S.C. § 1337 (1994) as a sanction for Genentech's purported violation of the ITC's discovery orders. *See In re Certain Recombinantly Produced Human Growth Hormones*, Inv. No. 337-TA-358 (Int'l Trade Comm'n Jan. 17, 1995) (decision denying review of final initial determination), *appeal docketed sub nom. Genentech, Inc. v. United States Int'l Trade Comm'n*, No. 95-1244 (Fed. Cir. Mar. 17, 1995). BTG contends that Genentech is attempting to relitigate in district court the same claim it lost before the ITC. We cannot accept this contention.

The decision of an administrative agency potentially may be given preclusive effect when, as here, the agency acted in a judicial capacity. *See University of Tenn. v. Elliott*, 478 U.S. 788, 797-99 (1986). That the ITC did not reach the substantive question of infringement does not prevent application of claim preclusion. *See Angel v. Bullington*, 330 U.S. 183, 190 (1947) ("It is a misconception of *res judicata* to assume that the doctrine does not come into operation if a court has not passed on the 'merits' in the sense of the ultimate substantive issues of a litigation.").

Under the principle of claim preclusion, "a party must raise in a single lawsuit all the grounds of recovery arising from a single transaction or series of transactions that can be brought together." *Mars Inc. v. Nippon Conlux Kabushiki-Kaisha*, 58 F.3d 616, 619, 35 USPQ2d 1311, 1314 (Fed. Cir. 1995); *see Woods v. Dunlop Tire Corp.*, 972 F.2d 36, 38 (2d Cir. 1992) (application of claim preclusion depends on whether the same transaction or series of transactions is at issue, whether the same evidence is needed to support both claims, and whether the facts essential to the second judgment were present in

the first); *Restatement (Second) of Judgments* § 24 (1982) (all actions arising from the same transaction or series of transactions constitute a single claim for purposes of claim preclusion).

However, the bar against later claims based on the same transactional facts is "subject to certain limitations, one of which is that it will not be applied if the initial forum did not have the power to award the full measure of relief sought in the later litigation." *Davidson v. Capuano*, 792 F.2d 275, 278 (2d Cir. 1986). As stated by the Restatement:

> The general rule [against relitigation of a claim] is largely predicated on the assumption that the jurisdiction in which the first judgment was rendered was one which put no formal barriers in the way of a litigant's presenting to the court in one action the entire claim including any theories of recovery or demands for relief that might have been available to him under applicable law. When such barriers in fact existed and were operative against a plaintiff in the first action, it is unfair to preclude him from a second action in which he can present those phases of the claim which he was disabled from presenting in the first.

Restatement § 26(1)(c) cmt. c. "Thus, where a plaintiff was precluded from recovering damages in the initial action by formal jurisdictional or statutory barriers, not by plaintiff's choice, a subsequent action for damages will not normally be barred by res judicata even where it arises from the same factual circumstances as the initial action." *Burgos v. Hopkins*, 14 F.3d 787, 790 (2d Cir. 1994).

This limiting principle is applicable here. Under section 337 of the Tariff Act of 1930 as amended, 19 U.S.C. § 1337, the ITC has the authority to investigate unfair practices in import trade, including:

> (B) [t]he importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that—

> (i) infringe a valid and enforceable United States patent . . . ; or
>
> (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

19 U.S.C. § 1337(a)(1)(B) (1994).

When the ITC determines that a defendant has engaged in unfair practices in import trade, it may direct that the articles at issue be excluded from entry into the United States, 19 U.S.C. § 1337(d), issue a cease and desist order, 19 U.S.C. § 1337(f), and/or issue an order providing that the articles in violation be seized and forfeited to the United States, 19 U.S.C. § 1337(i). Importantly, however, the ITC does not have the power to award damages for patent infringement. This form of relief may only be provided by the United States District Courts, which have original and exclusive jurisdiction over patent infringement cases. *See* 28 U.S.C. § 1338(a) (1994).

The legislative history of the Trade Reform Act of 1974 supports the view that ITC decisions with respect to patent issues should have no claim preclusive effect in later district court litigation:

> The Commission is not, of course, empowered under existing law to set aside a patent as being invalid or to render it unenforceable, and the extent of the Commission's authority under this bill is to take into consideration such defenses and to make findings thereon for the purposes of determining whether section 337 is being violated.
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> . . . [I]n patent-based cases, the Commission considers, for its own purposes under section 337, the status of imports with respect to the claims of U.S. patents. The Commission's findings neither purport to be, nor can they be, regarded as binding interpretations of the U.S. patent laws in particular factual contexts. Therefore, it seems clear that any disposition of a Commission action

> by a Federal Court should not have a res judicata or collateral estoppel effect in cases before such courts.

S. Rep. No. 1298, 93d Cong., 2d Sess. 196 (1974). We note that "the ITC takes the position that its decisions have no *res judicata* effect in [district court] litigation." *Corning Glass Works v. United States Int'l Trade Comm'n*, 799 F.2d 1559, 1570 n.12, 230 USPQ 822, 830 n.12 (Fed. Cir. 1986).

Thus, in view of the jurisdictional limitations on the relief available in the ITC, we hold that the ITC's prior decision cannot have claim preclusive effect in the district court. *See also Texas Instruments, Inc. v. United States Int'l Trade Comm'n*, 851 F.2d 342, 344, 7 USPQ2d 1509, 1510 (Fed. Cir. 1988) ("[T]his court has stated that the ITC's determinations regarding patent issues should be given no res judicata or collateral estoppel effect.").[9]

c. *Laches and Estoppel*

BTG also contends that laches bars Genentech's infringement counterclaim. BTG asserts that in 1985 and 1986, Genentech knew that BTG had developed an hGH product and imported it into the United States for use in clinical trials. BTG contends that Genentech should have brought suit against BTG soon after it learned of this information. We disagree.

Prior to 1988, when § 271(g) became effective, importation of a product made abroad by a process patented in the United States was not an act of infringement. Thus, Genentech had no infringement claim against BTG before 1988. With no legal right to enforce, it cannot be said that Genentech unreasonably delayed during that time period.

Furthermore, even after § 271(g) was enacted in 1988, BTG was only importing hGH into the United States for use in

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[9] In *Young Engineers, Inc. v. United States International Trade Commission*, 721 F.2d 1305, 219 USPQ 1142 (Fed. Cir. 1983), we held that a district court decision resolving a patent infringement claim may have claim preclusive effect in a subsequent § 1337 investigation based on the same assertion of infringement. *Id.* at 1313-16, 219 USPQ at 1150-52. For the reasons stated above, however, the reverse is not true.

clinical trials in support of its application for FDA approval. The district court found that this was non-infringing activity, *see* 35 U.S.C. § 271(e)(1) (1988),[10] and that Genentech did not know before 1993 that BTG had imported hGH into the United States for purposes outside the scope of § 271(e)(1). BTG has not demonstrated error in these findings. Thus, we conclude that the court did not err in rejecting BTG's laches defense.

BTG also argues, in conclusory fashion, that

> Genentech, through misleading conduct, led BTG to infer that Genentech did not intend to enforce the patents against it. BTG relied on such conduct, and will be severely harmed if Genentech now is permitted to enforce its patents. Thus, Genentech's infringement suit is barred under the doctrine of equitable estoppel.

We disagree. BTG cites no evidence to support its assertion; thus, on the present record, there is no factual basis for an estoppel defense.

d. *Validity/Enforceability*

BTG does not contend that the '980 and '832 patents are invalid in view of the prior art or for failure to meet the enablement or other requirements of 35 U.S.C. § 112. Rather, BTG argues, first, that Genentech admitted that its patent position is "weak." The district court did not err in rejecting this contention, because BTG relied on documents found inadmissible by the district court. On appeal, BTG has not demonstrated that the court's evidentiary ruling was in error; thus, we will not further consider this argument.

BTG also argues that the inventors named in the asserted patents did not actually conceive the inventions claimed therein. BTG again cites evidence that the district court found

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[10] In 1988, § 271(e)(1) provided that "[i]t shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. § 271(e)(1) (1988).

inadmissible, and BTG has not shown that the court's evidentiary ruling was erroneous. Thus, we reject this argument.

BTG further argues that Genentech "misappropriated inventions, materials, people and information" from the University of California ("UC"), and that the asserted patents are unenforceable because Genentech did not disclose its "misappropriation" to the United States Patent and Trademark Office during patent prosecution. We disagree. The district court found that BTG's witness on this issue, Dr. Goodman, gave testimony that "was at best inconclusive and entitled to no weight" and that he "did not provide any probative testimony in support of the allegation that Genentech misappropriated the inventions, or indeed, anything at all, from UC." On appeal, BTG has not shown that the district court erred in evaluating the credibility of Goodman's testimony. BTG addresses the Administrative Law Judge's findings in the ITC case; however, these arguments do not show error in the district court's findings.

BTG also argues that the unclean hands doctrine bars Genentech's infringement counterclaim, because Genentech allegedly violated the ITC's discovery orders and "misappropriated" the '980 and '832 inventions from scientists at the University of California. Again, we must disagree. These assertions are largely without evidentiary support in the record. In addition, as the district court found, the purported misconduct did not occur in the context of the present lawsuit. Thus, the court did not err in rejecting BTG's unclean hands defense. *See Warner Bros., Inc. v. Gay Toys, Inc.*, 724 F.2d 327, 334 (2d Cir. 1983) ("[T]he defense of unclean hands applies only with respect to the right in suit.").

We therefore conclude that BTG has not shown that the district court clearly erred in finding that Genentech established a reasonable likelihood of success on the merits of its infringement counterclaim.

B. *Irreparable Harm*

BTG next argues that the district court's finding of irreparable harm is clearly erroneous. We disagree. The court cor-

rectly held that Genentech was entitled to a presumption of irreparable harm because Genentech made a strong showing of infringement and validity, and BTG's asserted defenses lacked substantial merit. *See Nutrition 21*, 930 F.2d at 871, 18 USPQ2d at 1351 (district court may presume irreparable harm upon a clear showing of infringement and validity). BTG did not come forward with persuasive evidence to rebut the presumption of irreparable harm. In addition, the district court determined that Genentech would be harmed if BTG were allowed to enter the market because Genentech would lose revenues and goodwill, and would be required to reduce its research and development activities. BTG has not demonstrated that these findings are clearly erroneous.

C. *Other Factors*

The district court found that the balance of the hardships and the public interest favored entering a preliminary injunction. BTG challenges these findings; however, having carefully considered BTG's arguments, we find no error in the district court's analysis of these factors.

In addition, we have considered BTG's remaining arguments, including its contentions concerning alleged procedural errors, but find them unpersuasive.

CONCLUSION

The district court did not err in finding that Genentech established a reasonable likelihood of success on the merits of its infringement counterclaim. The court also did not err in finding that Genentech would suffer irreparable harm absent an injunction and that the balance of the hardships and public interest considerations favored the grant of an injunction. Further, the court did not make a clear error of judgment in weighing the relevant factors. Thus, we conclude that the court did not abuse its discretion by granting a preliminary injunction.

No costs.

AFFIRMED.

(FILED UNDER SEAL)

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Civil Action No. 95 Civ. 0110 (CBM)

BIO-TECHNOLOGY GENERAL CORP.

Plaintiff,

—against—

GENENTECH, INC.,

Defendant,

BIO-TECHNOLOGY GENERAL (ISRAEL), LTD.,

Additional Defendant On Counterclaims.

PRELIMINARY INJUNCTION ORDER

ORDER OF PRELIMINARY INJUNCTION

This cause came on to be heard on defendant's motion for a preliminary injunction and the court having considered the verified complaint, the affidavits submitted in support of said motion and in opposition thereto, and having heard oral evidence and received exhibits in court, and the court having made and filed its finding of fact and conclusions of law, it is

NOW ORDERED, ADJUDGED, and DECREED that

Bio-Technology General Corp., Bio-Technology General (Israel) LTD, and their parents, subsidiaries, agents, employees, attorneys and all those acting in concert with each of them who receive actual notice of this injunction order are hereby enjoined, pending the final determination of this action, from importing, making, using, selling, offering for sale or distributing in the United States, Bio-tropin, Human Growth Hormone, except for current bona fide continuing Food & Drug Administration (FDA) approved clinical dosing trial.

This order shall be effective immediately upon payment by Genentech of cash or a surety bond that meets the satisfaction of the Clerk of the Court in the amount of $250,000 pursuant to Federal Rule of Civil Procedure 65(c).

SO ORDERED.

Dated: August 10, 1995
New York, New York

/s/ CONSTANCE BAKER MOTLEY
Constance Baker Motley
U.S.D.J.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Civil Action No. 95 Civ. 0110 (CBM)
[ ]*

BIO-TECHNOLOGY GENERAL CORP.

Plaintiff,

—against—

GENENTECH, INC.,

Defendant,

BIO-TECHNOLOGY GENERAL (ISRAEL), LTD.,

Additional Defendant On Counterclaims.

FINDINGS OF FACT AND CONCLUSIONS OF LAW PUBLIC VERSION

This case is now before the court on the motion of defendant, Genentech, Inc., for a preliminary injunction enjoining the plaintiff and the additional defendant on its counterclaim from infringing its human growth hormone patents. For the reasons set forth below, the motion is granted.

Genentech, Inc. ("Genentech") hereby submits its proposed findings of fact and conclusions of law in support of its motion for a preliminary injunction.

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* Bold brackets with five spaces in between indicate confidential material deleted from public version of opinion.

I. BACKGROUND

A. *Procedural Background*

1. On December 1, 1994 Genentech commenced an action against, *inter alia*, Bio-Technology General Corp. ("BTG Corp.") and Bio-Technology General (Israel) LTD. ("BTG Israel"; BTG Corp. and BTG Israel are referred to herein collectively as "BTG") in the United States District Court for the District of Delaware alleging that BTG had infringed certain of Genentech's patents. (Delaware Complaint). Genentech alleged infringement by BTG of Genentech's United States Patent Nos. 4,601,980 (the '980 patent) and 4,342,832 (the '832 patent) (Delaware Complaint, ¶¶ 9, 10). BTG filed a motion to transfer that action to the Southern District of New York which was granted.

2. About a month later, on January 6, 1995, BTG Corp. filed the present action against, *inter alia*, Genentech in which it seeks a declaratory judgment that the '980 and '832 patents, and United States Patent No. 5,221,619 (the '619 patent) are invalid, unenforceable and not infringed by BTG Corp. (Amended Complaint, ¶¶ 17-24, 29-42; the first, third and fourth claims for relief), a declaratory judgment that Genentech was barred from asserting the '832, '980 and '619 patents against BTG Corp. under the doctrine of *res judicata* because of a determination of the International Trade Commission ("ITC") (Amended Complaint, ¶¶ 25-28, the second claim for relief) and also asserted various nonpatent federal and state law claims. The case was initially assigned to the Honorable Robert P. Patterson, Jr., but on February 28, 1995 was transferred to this court as a related case.

3. On April 7, 1995, Genentech filed its Amended Answer and Counterclaims against BTG (Genentech named BTG Israel as an additional counterclaim defendant) in which Genentech alleges that BTG has willfully and deliberately infringed the '980, '832 and '619 patents.

4. On or about May 25, 1995, BTG Corp. received approval from the United States Food and Drug Administra-

tion ("FDA") to market and sell its human growth hormone ("hGH") product, Bio-Tropin™, in the United States.

5. On May 30, 1995, Genentech moved, by order to show cause, for a temporary restraining order and a preliminary injunction prohibiting BTG from importing, marketing and selling Bio-Tropin™ in the United States in violation of the '980 and '832 patents. This court denied the application for a temporary restraining order but scheduled an expedited hearing on Genentech's motion for a preliminary injunction. (Transcripts of Hearings before Judge Motley, May 30, 1995 and May 31, 1995).

6. Beginning on June 19, 1995, and concluding on June 27, 1995, the court held an evidentiary hearing on Genentech's motion for a preliminary injunction. During the hearing, BTG stipulated [ ] pending this court's ruling on Genentech's motion. (Tr., p. 418).

B. *The Parties*

7. Genentech is a Delaware corporation with its principal place of business in South San Francisco, California.

8. BTG Corp. is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 70 Wood Avenue South, Metro Park Financial Center, 2nd Floor, Iselin, New Jersey 08830. Prior to October, 1993, BTG Corp. had its principal place of business at 1250 Broadway, New York, New York. (BTG Corp.'s Amended Complaint, ¶ 3).

9. BTG Israel is a corporation organized and existing under the laws of Israel, having its principal place of business at Kiryat Weizman Industrial Park, Rehovot, Israel 76326. BTG Israel is a wholly-owned subsidiary of BTG Corp.

III. LIKELIHOOD OF SUCCESS ON THE MERITS

A. *Related Proceeding Before the International Trade Commission*

10. In a prior proceeding before the International Trade Commission Genentech alleged that BTG was infringing, *inter alia*, the '980 and '832 patents by importing Bio-Tropin™. *In the Matter of Certain Recombinantly Produced Human Growth Hormones*, ITC Inv. No. 337-TA-358 ("ITC Proceeding"). In his Initial Determination issued on November 29, 1994, the Administrative Law Judge ("ALJ") found, based on what he characterized as an incomplete record, that the '980 and '832 patents were not invalid and were infringed by BTG. (Def. Exs. 6, 7, 8 and 9). The ITC proceeding was dismissed by the ITC following the Initial Determination of the ALJ as a sanction for what he found was non-compliance with discovery requirements. Genentech has appealed the ITC's decision to the United States Court of Appeals for the Federal Circuit.

11. The ALJ held his decision to be based on an incomplete record because Genentech had not produced certain documents which Genentech characterizes as privileged but which the ALJ held were not privileged based on waiver. While the ALJ's decision is based on a potentially incomplete record should the documents be determined to have been waived, the ALJ nonetheless made detailed findings and conclusions based on an evidentiary record on the merits.

12. This court thus takes judicial notice of the ALJ's decision that Claim 2 of the '980 patent and Claim 1 of the '832 patent are not invalid and are infringed by BTG. It has considered that decision as one among many factors supporting its conclusion of a strong likelihood of success on the merits on a trail by Genentech. This court, as indicated below, has independently made its own findings of law and conclusions of law with respect to the likelihood of success on the merits.

B. *Interpretation Of Terms In The Technological Background*

13. An organism's genetic information is contained in a molecule called "DNA" or deoxyribonucleic acid. (Tr. 49, Falkinham; Def. Exs. 18 and 59). DNA is a code which is "expressed", i.e., the genetic information provides a code the cell uses to make specific proteins. (Tr. 72, Falkinham). "Expression" consists of the "transcription" and "translation" of a DNA sequence. (Tr. 71, 111, Falkinham; Def. Ex. 59; Def. Ex. 1, col. 1, l. 10-28; Def. Ex. 3, col. 1, l. 8-26). The result of expression is an "expression product" called a protein, a linked sequence of amino acids. (Tr. 61, 64 and 83, Falkinham; Def. Ex. 57).

14. In gene expression, first the DNA sequence (containing the genetic information) is copied into a molecule called mRNA (or messenger ribonucleic acid), during a process called "transcription." (Tr. 51, Falkinham; Def. Ex. 59). The RNA transcription product is referred to as "messenger RNA", because it carries the genetic recipe for the protein from the DNA to the protein building machinery of the cell called the ribosome. (Tr. 48, Falkinham; Def. Ex. 1, col. 1, l. 20-23). Messenger RNA is a molecule that serves as an intermediate between the genes in the nucleus of a cell made of DNA and the resulting protein. (Tr. 48, Falkinham).

15. In the second part of the expression process, "translation", the ribosome reads each three letter codon of "messenger RNA" and "translates" each three letter codon in RNA to a single amino acid. (Tr. 66, 185-187, Falkinham; Def. Ex. 1, col. 1, l. 24-28). In order for the ribosome to correctly "read" the three letter codons of messenger RNA, codons must be in proper reading phase relative to the start codon. (Tr. 186-188, Falkinham; Def. Ex. 13; Def. Ex. 1, col. 1, l. 29-33). During translation, the ribosome actually binds to the RNA molecule and starts protein synthesis where it encounters the AUG codon. It then moves down the mRNA reading three letter codons containing the information encoding separate amino acids. (*Id.*; Def. Ex. 53; Def. Ex. 1, col. 1, l. 24-

28). "Expression" is complete when translation has been completed. In order to express any gene there must be a start codon, i.e. AUG. (Tr. 92, 274, Falkinham). As a result, the expression product always begins with methionine, the amino acid encoded by the start codon (i.e., ATG in DNA, which is the codon AUG in the corresponding mRNA). (Tr. 92, 274, Falkinham; Def. Ex. 1, col. 1, l. 24-28; Def. Ex. 3, col, 1, l. 22-26).

16. Enzymes are proteins and perform certain functions. (Tr. 50 Falkinham). For example, the enzyme "RNA polymerase" recognizes and binds sequences in DNA thus directing the synthesis of mRNA. (Tr. 50, Falkinham). The sequences that the RNA polymerase recognizes are called expression promoters. (Tr. 50, 182, Falkinham; Def. Ex. 22). An expression promoter is a DNA sequence which allows the enzyme RNA polymerase to bind to the sequence, begin moving along the sequence and direct the synthesis of a messenger RNA. (Tr. 111, Falkinham). Another example of an enzyme is "reverse transcriptase". (Tr. 51, Falkinham). Reverse transcriptase performs the function of using an mRNA molecule to make a DNA copy of that molecule. (*Id.*; Def. Ex. 18). Since molecular biologists call the process of going from DNA to RNA transcription, they call the enzyme that performs the reverse role in making DNA from RNA reverse transcriptase—it reverses the transcription process. (Tr. 51, Falkinham; Def. Ex. 18). By convention, DNA which is made by using reverse transcriptase is called "cDNA" —with "c" meaning copy or complementary. (Tr. 52, 109-110, Falkinham; Def. Ex. 1, col. 3, l. 12-35 and col. 8, l. 13-16); *Id.*

17. Naturally occurring hGH produced in cells of the human pituitary includes a series of amino acids called the "leader sequence"; the pituitary cells remove from hGH the leader sequence as it emerges from the cell. (Tr. 52, Falkinham). Cells from the human pituitary can be used to prepare cDNA for human growth hormone, including its leader. (Tr. 52, Falkinham). RNA polymerase can be used to make mRNA corresponding to hGH DNA and its leader, and then reverse

transcriptase can be used to make cDNA from the messenger RNA encoding hGH and its leader. (Tr. 52-52, 223, 241, Falkinham; Def. Ex. 18).

18. The term "organically synthesized" or "synthetic" refers to chemically synthesizing the nucleotide building blocks of selected DNA molecules. (Tr. 55, Falkinham; Def. Ex. 1, col. 9, l. 42 through col. 10, l. 19). A "quasi-synthetic" gene contains a portion which is organically (chemically) synthesized and a portion which can be cDNA (produced utilizing reverse transcriptase); the portions are combined. (Tr. 71-72, Falkinham; Def. Ex. 1, col. 4, l. 3-11, col. 4, l. 68 through col. 5, l. 9; col. 10, l. 20 through col. 11, l. 26).

19. An "inclusion body" (also referred to as a refractile body) is sometimes seen through a microscope as a spot in a cell containing large clumps of an expression product. (Tr. 84, Falkinham). During expression, many chains of the expression product (protein) are produced like beads on a string. They often aggregate together. (Tr. 85-86, Falkinham). When the chains of expression product aggregate together, they are not properly folded, and for that reason, are not biologically active. (Tr. 85-86, 277-279, Falkinham). Following expression, it is necessary to engage in isolation and purification, in part for the purpose of unwinding these aggregates of the expressed product so that they can become properly folded and biologically active. (Tr. 85 - 87, 277-279, Falkinham). Recombinant expression products, whether formed as inclusion bodies or otherwise, are biologically inactive within the cell until isolated and purified. (*Id.*)

20. Recombinant DNA technology involves the use of cloning technology to induce bacterial hosts to produce useful synthesized human proteins in abundant quantities. (Tr. 68-70, Falkinham). "Cloning" is a process that allows one to isolate a single gene or sets of genes from the entire genetic information of an organism, and then place it specifically into bacteria or other organisms (Tr. 62-63, Falkinham). In bacteria, there exist small genetic elements called "plasmids" which are illustrated as "circles" of DNA and have the

property of being able to replicate (copy themselves) independently from the host chromosome. (Tr. 60 Falkinham). Because of this property, it is possible to cut plasmids open and insert pieces of other DNA into them and, when such an insertion has been done, the plasmid can be placed into bacteria where it will replicate and thus propagate. (Tr. 69, Falkinham). This is the cloning process. (Tr. 62-69, Falkinham). These plasmids are also called "cloning vehicles." (Def. Ex. 1, col. 2, l. 20-23; Tr. 60, 68-70, Falkinham). The bacterial host is induced to "express"—transcribe and translate—a gene for a protein contained in the plasmid and thus produces an expression product, which is then isolated and purified to a biologically active state. (Def. Ex. 1 col. 13, l. 15-16; Def. Ex. 3, col. 13, l. 15-16; Tr. 261, Falkinham).

C. *The Inventions of the '980 and '832 Patents*

21. The '980 patent, entitled MICROBIAL EXPRESSION OF A GENE FOR HUMAN GROWTH HORMONE, was issued on July 22, 1986 to David V. Goeddel and Herbert L. Heyneker and is assigned to Genentech. (Def. Ex. 1). Genentech originally applied for this patent on July 5, 1979. (*Id.*). The '980 patent expires on July 22, 2003. The '980 patent was subject to a request for reexamination in the Patent Office. (Def. Ex. 2). The validity of the '980 patent was also challenged in the ITC Proceeding. (Def. Exs. 6-7).

22. The '980 patent claims methods of producing hGH recombinantly (Tr. 80, Falkinham; Def. Ex. 1) and, in particular, methods for expressing human growth hormone genes in bacterial hosts (Tr. 80, Falkinham; Def. Ex. 1, col. 14). Met-hGH and hGH are among the possible human growth hormone products that can be produced using the methods of the '980 patent—met-hGH has 192 amino acids and hGH has 191 amino acids. (Tr. 81-82, Falkinham). The methods of the '980 patent cover the use of a gene encoding, *inter alia*, the amino acids of met-hGH. (*Id.*)

23. In simplest terms, the invention of the '980 patent involves installing, in a bacterial cell, a gene for human

growth hormone which the cell can transcribe and translate, i.e., "express." (Tr. 81-82, Falkinham). These cells provide a new source from which an amino acid sequence containing hGH is recovered and processed to produce hGH or met-hGH, both suitable for the treatment of growth hormone deficiency. (*Id.*; Def. Ex. 1). Both met-hGH and hGH are bioactive. (Def. Ex. 1, col. 7, l. 55-57). Met-hGH is Protropin® sold by Genentech; hGH without the "met" is sold as Nutropin® by Genentech (and is also sold as Humatrope®, by Lilly). (Tr. 293, Blizzard; 154, Matlock).

24. The '832 patent, entitled METHOD OF CONSTRUCTING A REPLICABLE CLONING VEHICLE HAVING QUASI-SYNTHETIC GENES, was issued on August 3, 1982 to David V. Goeddel and Herbert L. Heyneker, and is assigned to Genentech. (Def. Ex. 3). The '832 patent was subject to a request for reexamination in the Patent Office. (Def. Ex. 4). The '832 patent expires on August 3, 1999. The validity of the '832 patent, like that of the '980 patent, was also challenged in the ITC Proceeding. (Def. Exs. 8-9).

25. The '832 patent claims methods for the general construction of semisynthetic genes capable of producing polypeptides in bacterial hosts, without limitation to human growth hormone. (Def. Ex. 3). The preferred embodiment of the '832 patent as set forth in Figure 5 thereof is a quasi-synthetic gene, incorporating a combination of cDNA and organically synthesized DNA into a recombinant cloning vehicle capable of producing human growth hormone in a bacterial host. (Tr. 94-95, Falkinham).

26. In simplest terms, the method of the '832 patent involves making a plasmid which includes cDNA encoding the amino acids for a large portion of a gene (e.g. Def. Ex. 3, Figure 5 (amino acids 24-191 of hGH)), preparing an organically synthesized fragment of DNA encoding the remaining portion of the hGH gene, and joining together the cDNA fragment and the organically synthesized fragment into a cloning vehicle capable of expressing a protein—here hGH—in bacteria. (Tr. 95-97, Falkinham; Def. Ex. 3).

D. *The Problem Solved By The '980 and '832 Patents*

27. When the inventors of the '980 and '832 patents, Genentech scientists David Goeddel and Herbert Heyneker, set out to produce human growth hormone, their initial challenge was to obtain an hGH gene that could be used to produce active hGH recombinantly. (Def. Ex. 2, p. 52).

28. Making hGH from sources such as cDNA or genomic DNA presented a problem. These sources of DNA for hGH encode the desired protein and the "leader sequence". (Tr. 52, Falkinham; Def, Ex. 1, col. 3, l. 24-35). The leader sequence is there to help the hGH emerge from the pituitary cell after expression. It is clipped off automatically in nature as the hGH leaves the pituitary cell. (Tr. 72, Falkinham). Prior to the inventions of the '980 and '832 patents, no one was able to figure out how to obtain hGH recombinantly without the leader. (Def. Ex. 1, col. 3, l. 24-35; Def. Ex. 56, Tr. 71-74, 82-83, Falkinham). In bacteria, the leader of hGH is not clipped off automatically. (Tr. 73-75, 82-83, Falkinham; Def. Ex. 56). The leader thus remains attached to the hGH and renders it non-functional. (Def. Ex. 1, col, 3; Tr. 74, 82-83, Falkinham).

29. The leader sequence problem was the subject of a speech by Dr. Goodman on August 16-20, 1978, at the Proceedings of the Alfred Benzon Symposium. (Tr. 74 and 82-83; Def. Ex. 2 (reexamination), p. 73). Dr. Goodman, at the time a highly skilled molecular biologist at the University of California involved in efforts to develop recombinant growth hormones, stated that he had succeeded in obtaining the rat growth hormone gene only *with the complete leader sequence*, and that he had very few ideas about how to remove the leader sequence. (*Id.*). Goodman's unworkable solution is reflected in the file history of the '980 patent as the Goodman work and the Martial work. (Def. Ex. 2, pp. 118-120; Def. Ex. 56).

30. The '980 and '832 patents provide the solution to the leader sequence problem. As indicated in the preferred embodiments of the '980 and '832 patents, the inventors took

cDNA encoding both hGH and its leader sequence, cut off a portion of the cDNA (coding for the leader sequence and part of the hGH gene) and were left with codons 24-191 of hGH. (Def. Ex. 1, col. 10, l. 63-68; Tr. 95-97, Falkinham). The solution involved replacing the cDNA encoding the first 23 amino acids of hGH with the first 23 codons for hGH protein from other sources. (Tr. 96, Falkinham). In the preferred embodiment of the '980 and '832 patents, a chemically synthesized DNA fragment corresponding to the 23 codons missing from the cDNA hGH fragment plus a "start" codon ("ATG"—coding for the amino acid methionine) was fused to the remaining 24-191 cDNA hGH fragment. (*Id.*, col. 9, l. 36 to col. 10, l. 19, col. 10,1. 44 to col. 11, l. 5). The resulting "semi-synthetic" gene was then inserted in a bacterial cell and artificially produced for the first time functional hGH. (Def. Ex. 1, col. 11, l. 28-31).

E. *Claim Interpretation And Infringement*

31. The Federal Circuit has held that the interpretation and construction of a patent claim is a matter of law to be determined exclusively by the court. *Markman* v. *Westview Instruments, Inc.*, __ F.3d __, 34 U.S.P.Q. 2d 1321, 1322 (Fed. Cir. 1995) (en banc). To determine the meaning of claims, courts look to the claim language, the specification, and the prosecution history. *Unique Concepts, Inc.* v. *Brown*, 939 F.2d 1558, 1561 (Fed. Cir. 1991); *SmithKline Diagnostics* v. *Helena Laboratories Corp.*, 859 F.2d 878, 882 (Fed. Cir. 1988); *Minnesota Mining and Manufacturing Co.* v. *Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1576-77 (Fed. Cir. 1992). The prosecution history "is of primary significance in understanding the claims" because it provides an " 'undisputed public record' " of the proceedings in the Patent and Trademark Office. *Markman*, 34 U.S.P.Q. 2d at 1330. Extrinsic evidence, such as expert and inventor testimony, dictionaries, and learned treatises, also are relevant to the interpretation of patent claims. *Id.* at 1331; *see also SmithKline*, 859 F.2d at 882. Additionally, claims should be "construed as one skilled in the art would construe them."

SmithKline, 859 F.2d at 882; *Markman*, 34 U.S.P.Q. 2d at 1329.

32. The determination of infringement is a two-step process. First, the language of the claims must be interpreted; and second, the accused device or process must be compared to the claim language as properly interpreted. *Read Corp.* v. *Portec, Inc.*, 970 F.2d 816, 822 (Fed. Cir. 1992). In evaluating infringement it should be kept in mind that the '980 and '832 patents represent pioneering contributions by Goeddel/Heyneker to the basic development of the biotechnology industry. As such, the '980 and '832 patents are entitled to a broad construction consistent with the scope and importance of their achievements. *Texas Instruments, Inc.* v. *U.S. Intern. Trade Com'n.*, 846 F.2d 1369, 1370 (Fed. Cir. 1988). These principles, and Claim 2 of the '980 patent and Claim 1 of the '832 patent, element by element, are applied to BTG's Bio-Tropin™ process below.

(1) *Claim 2 Of the '980 Patent*

33. Claim 2 of the '980 patent is the only claim relied upon for this motion. (Def. Ex. 1, col. 14). During the hearing, Genentech offered the only interpretation of the '980 patent, and an application of that claim to BTG's process for making hGH, through its expert Dr. Falkinham, which BTG did not dispute. This court has also previously interpreted Claim 2 of the '980 patent in its decision of June 28, 1995 in *Novo Nordisk A/S et al.* v. *Genentech*, Civ. Action No. 94-8634 (CBM). In its own review of the claim, the specification and the file history, this court agrees with the interpretation of Claim 2 advanced by Dr. Falkinham (Tr. 76-94 and 210, Falkinham; Def. Exs. 55-57). BTG's method for making Bio-Tropin™, its product, is described in BTG's New Drug Application to the FDA for Bio-Tropin™. (Def. Ex. 11). As explained below, BTG infringes Claim 2 of the '980 patent. (Tr. 58, Falkinham; Def. Ex. 18).

34. BTG's process for expressing human growth hormone includes the steps of each and every element of Claim 2 of the

'980 patent: (a) first, BTG "cultures bacterial transformants" meaning placing [ ] in an environment so that it can grow and express genes (Tr. 58-59, 77, Falkinham; Def. Ex. 11 at 000182 and 000305-313; Def. Ex. 18); (b) second, BTG's bacterial transformants contain a recombinant plasmid [ ] as that term is used in Claim 2 of the '980 patent (Tr. 77-78, Falkinham; Def. Ex. 11 at 000182 and 000305-313; Def. Exs. 18 and 55); (c) third, in a "transformant bacterium", or bacterial host, BTG's plasmid will "express [transcribe and translate] a gene for human growth hormone" and, in particular, [ ] (Tr. 60-61, 80-81, Falkinham); (d) fourth, BTG expresses hGH "unaccompanied by the leader sequence of human growth hormone" because [ ] without the leader sequence of human growth hormone and [ ] (Tr. 82-83, Falkinham); (e) fifth, BTG expresses hGH without "other extraneous protein bound thereto" (meaning without other protein such as the leader sequence that could not be cleaved) because BTG's expression product is [ ] without any other protein (Tr. 64-83, Falkinham); and (f) sixth, BTG then isolates and purifies the [ ] expression product utilizing a number of steps, [ ] (Tr. 83, Falkinham; Def. Ex. 11, p. 000333-334, 000181-183; Def. Exs. 18 and 55).

35. BTG apparently contends that it does not infringe the '980 patent because: (1) it recovers [ ] from so-called "inclusion bodies" or refractile bodies; and (2) until it recovers and purifies the [ ] from the inclusion bodies, the [ ] is not properly folded and therefore biologically inactive. This court rejects these contentions.

36. As Genentech's expert, Dr. Falkinham, explained, the fact that the expression product in the BTG process forms inclusion bodies does not mean that the expression product is not [ ] (Tr. 85, Falkinham). Moreover, BTG ignores the fact that the [ ] that is described in the '980 patent, although not aggregated as inclusion bodies, is not properly folded and that one of the purposes of the isolation and purification portion of the process of the '980 patent is to separate and purify [ ] so that the [ ] becomes properly folded and biologically active. (Tr. 85-88, 278, Falkinham). Indeed, by isolating

and purifying the [ ] from the inclusion bodies, BTG's process explicitly follows one of the steps of the '980 patent. [ ]

37. In the NDA for its Bio-Tropin™ hGH product, BTG admits that its [ ] of inclusion bodies are purification processes. (Def. Ex. 11, pp. 000333-334). Claim 2 of the '980 patent expressly states that the process of the invention involves "isolating and purifying said expressed human growth hormone". Thus, BTG's [ ] of inclusion bodies are purification processes which clearly are covered by the language in Claim 2 of the '980 patent.

38. BTG also contends that its process involves purported improvements over the process of the '980 patent insofar as it [ ] from its [ ] expression product. However, BTG ignores the fact that Claim 2 of the '980 patent recites a method which "comprises" several steps. In patent law, the term "comprises" is a term of art which means that Claim 2 does not exclude additional unrecited elements. *E.g.*, *Moleculon Research Corp.* v. *CBS, Inc.*, 793 F.2d 1261 (Fed. Cir. 1986), *cert. denied*, 479 U.S. 1030 (1987)). All that is necessary for infringement is that BTG's method includes the elements of Claim 2. This court notes that BTG's claim that it has an improved product by [ ] is highly suspect. Genentech's expert, Dr. Robert Blizzard, testified that from a medical and scientific standpoint, Genentech's 192 amino acid "met-hGH" product and a 191 amino acid hGH product perform the identical function and are equally safe and effective. (Tr. 293, Blizzard).

39. Even assuming that the BTG process may involve improvements over the processes of Claim 2 of the '980 patent, as a matter of law BTG's improved process nonetheless infringes. A patent on the improvement carries no right to practice the invention in violation of the rights of the owner of the patent on the basic or broad invention. *See, e.g.*, *Richardson* v. *Suzuki Motor Co. Ltd.*, 868 F.2d 1226, 1240 (Fed. Cir.), *cert. denied*, 493 U.S. 853 (1989) ("A device that embodies improvements on a claimed structure does not auto-

matically avoid the reach of the claim."); *Atlas Powder Co.* v. *E. I. Du Pont de Nemours & Co.*, 750 F.2d 1569, 1580 (Fed. Cir. 1984), ("[W]here [the] defendant has appropriated the material features of the patent in suit, infringement will be found even when those features have been supplemented and modified to such an extent that the defendant may be entitled to a patent for the improvement,"). Furthermore, as the Federal Circuit has held, "an embellishment' made possible by technological advances may not permit an accused device to escape the web of infringement.' " *Datascope Corp.* v. *SMEC, Inc.*, 776 F.2d 320, 326 (Fed. Cir. 1985).

(2) *Claim 1 of the '832 Patent*

40. Claim 1 of the '832 patent is the only claim relied upon for this motion.

(Def. Ex. 3, col. 13, l. 5-42).

41. During the hearing, Genentech presented the only interpretation of Claim 1 of the '832 patent, and an application of that claim to BTG's process for making its cloning vehicle, through its expert Dr. Falkinham, which BTG did not dispute. Again, this court has conducted its own review of the claim, the specification and the file history and agrees with the interpretation of Claim 1 of the '832 patent put forward by Dr. Falkinham. (Tr. 94-112 and 180-204, Falkinham; Def. Exs. 58A-B and 60A-C).

42. BTG's process for constructing the recombinant plasmid which it uses to produce its Bio-Tropin™ hGH product is [ ] the '832 patent. The preferred embodiment of the '832 patent, which Genentech practices in producing its Protropin® hGH product, is set forth in Figure 5 thereof. (Def. Ex. 3, Fig. 5; Tr. 95-97, Falkinham; Def. Exs. 11, 18, 58 and 60 A-C).

43. BTG practices the invention which comprises subparagraphs (a) through (d) of the method of the '832 patent as follows: BTG practices subparagraph (a) [ ] (Tr. 101 and 199-201, Falkinham; Def. Exs. 18 and 60B). BTG practices

subparagraph (b) [ ] (Tr. 201-204, Falkinham; Def. Ex. 60B, Def. Ex. 18) [ ] (Tr. 103-104, 201-204, Falkinham; Def. Ex. 18, Def. Ex. 60B). BTG practices subparagraph (c) [ ] (Tr. 110-111, 204-205, Falkinham; Def. Ex. 60C, Def. Ex. 18). [ ] (Tr. 206, Falkinham). BTG practices subparagraph (d) [ ] (Tr. 111, 207-210, Falkinham; Def. Ex. 60C; Def. Ex. 18).

44. BTG contends that it does not infringe the '832 patent because it made its plasmid [ ] only once in Israel in 1983—after the '832 patent issued—and never made it again. (Tr. 421, Gorecki). BTG argues that its one time use of the process of the '832 patent in Israel in 1983 cannot constitute an infringement because in 1983 the U.S. patent laws would not have made it an act of infringement for BTG to utilize the process of the '832 patent outside of the United States to produce a recombinant plasmid which would be utilized in subsequent years to manufacture an hGH product for importation into the United States. This contention raises a legal issue of first impression.

45. In 1988, Congress enacted 35 U.S.C. § 271(g) to extend liability for patent infringement to the use of a process to manufacture a product which is then imported into the United States. The pertinent portion of § 271(g) reads:

> Whoever, without authority imports into the United States or sells or uses within the United States a product which is made by process patented in the United States shall be liable as an infringer, if the importation, sale, or use of the product occurs during the term of such process patent. . .

46. Claim 1 of the '832 patent discloses a method for making replicable cloning vehicles and there is no dispute that BTG does not import the plasmid itself into the United States. The legal issue is whether BTG's use of the process of the '832 patent to make a replicable cloning vehicle containing the [ ] gene that is then cloned and used in the production of Bio-Tropin™, the product which is (or will be) imported into the United States, constitutes infringement. The legislative

history of § 271(g) addresses the precise situation that is presented in this case. The Senate Report states:

> In the biotechnology field it is well known that naturally occurring organisms contain within them particular genetic sequences composed of unique structural characteristics. The patented process may be for the process of preparing a DNA molecule comprising a specific genetic sequence. A foreign manufacturer uses the patented process to prepare the DNA molecule which is the product of the patented process. The foreign manufacturer inserts the DNA molecule into a plasmid or other vector and the plasmid or other vector containing the DNA molecule is, in turn, inserted into a host organism; for example, a bacterium. The plasmid-containing host organism still containing the specific genetic sequence undergoes expression to produce the desired polypeptide. Even if a different organism was created by this biotech procedure, if it would not have been possible or commercially viable to make the different organism and product expressed therefrom but for the patented process, the [polypeptide] product will be considered to have been made by the patented process.

(S. Rep. 100-83, 100th Cong., 1st Sess. at 51). This is what BTG has done. Thus, the legislative history clearly indicates that § 271(g) was intended to cover later produced biotechnology products made by a patented process even if the ultimate product imported and sold in the United States—in this case hGH—is a number of steps away from the original product of the patented process—in this case a [ ] recombinant cloning vehicle. BTG's importation of hGH derived from a recombinant cloning vehicle that is made pursuant to the process of the '832 patent clearly falls squarely within the description in the above-referenced legislative history of products that the statute intended to cover. Thus § 271(g) covers BTG's making [ ] and inserting clones of that plasmid into a host bacterium to make an hGH product.

47. BTG's next contends that it materially changes the product of its process [ ] is clearly unavailing. [ ] are encompassed by the patent claims. Thus, any change by BTG [ ] is not material and is still covered by the asserted claims. Moreover, the above-cited legislative history makes clear that BTG does not avoid infringement by its [ ] because "it would not have been possible or commercially viable" to make BTG's Bio-Tropin™ hGH product but for BTG's use of the patented process to construct its recombinant cloning vehicle. Indeed, but for BTG's use of the process in Genentech's '832 patent to construct a recombinant cloning vehicle, BTG's hGH product could not have been made. (Tr. 444-445 Gorecki). The court concludes that to permit BTG to escape liability on its material change theory would thwart the intent of Congress in enacting § 271(g) to provide patent protection in the field of biotechnology.

48. The court takes judicial notice that in the ITC Proceeding, the ALJ also concluded that Section 271(g) was intended to cover BTG's use of the process of the '832 patent to construct a recombinant cloning vehicle which it uses in connection with manufacturing hGH for importation into the United States. After independently reviewing the evidence and the legislative history, this court agrees with the conclusions of the ALJ on this issue.

49. BTG finally contends that it does not infringe the '832 patent because it [ ] for hGH from [ ] and, thus, did not follow subparagraph "a" of Claim 1 to utilize [ ] However, as a scientific matter, [ ] have been utilized to [ ] gave to BTG and, thus, the [ ] utilized by BTG was derived from the process of subparagraph "a" of Claim 1. (Tr. 223-224, Falkinham). Moreover, at the relevant time, [ ] was on BTG's Scientific Advisory Board (Tr. 426-428, Gorecki; Ex. Def. Ex. 136) and for purposes of determining whether BTG infringes Claim 1, [ ] as required by Claim 1 of the '832 patent are attributed to BTG. In any event, liability for infringement is not avoided where someone else performs one step of the patented process. *Idacon, Inc.* v. *Central Forest Products, Inc.*, 3 U.S.P.Q.2d 1079, 1092 (C.D. Okla. 1986);

Shields v. *Halliburton Company*, 493 F. Supp. 1376, 1389 (W.D.La. 1980).

50. Based on the foregoing, this court finds that Genentech has established a strong likelihood of success on the merits of its patent infringement claim against BTG based on the '980 and '832 patents.

G. *Validity and Enforceability of the '980 and '832 Patents And Alleged Inequitable Conduct*

51. The '980 and '832 patents are presumed valid under 35 U.S.C. § 282. The determination of whether Genentech has demonstrated a reasonable likelihood of success must be made in the context of the presumption of validity that the '980 and '832 patents will enjoy at trial and BTG's heavy burden of establishing invalidity by clear and convincing evidence. *Orthokinetics Inc.* v. *Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1570 (Fed. Cir. 1986); *H.H. Robertson, Co.* v. *United Steel Deck, Inc.*, 820 F.2d 384, 388 (Fed. Cir. 1987). For Genentech to meet its burden on likelihood of success on validity, it must only show that it is likely that BTG will not prove invalidity by clear and convincing evidence. Genentech has met its burden.

52. The burden is on BTG to come forward with an affirmative defense to the validity of the patent. *Roper Corp.* v. *Litton Sys. Inc.*, 757 F.2d 1266, 1270 (Fed. Cir. 1985); *New England Braiding Co., Inc.* v. *A.W. Chesterton Co.*, 970 F.2d 878, 882 (Fed. Cir. 1992). The Patent Office's denial of the requests for reexamination of the '980 and '832 patents (*i.e.*, requests that the Patent Office revisit the patentability of the inventions in view of "new" prior art) further strengthens the presumption of validity. *See Hewlett-Packard Co.* v. *Bausch & Lomb Inc.*, 909 F.2d 1464, 1467 (Fed. Cir. 1990).

53. In contending that the '980 and '832 patents are invalid and unenforceable, BTG has not asserted that the patents are invalid or obvious over the prior art.[1] Rather, BTG asserts

[1] Even if this court construes BTG's allegations as including a prior art invalidity defense, this court rejects it: The only prior art pos-

only that: (a) Genentech withheld material information from the Patent Office by failing to disclose that it had purportedly misappropriated the inventions of the patents from The Regents of the University of California ("UC"); and (b) the inventors named on the patents are not the true inventors. For the reasons set forth below, BTG's contentions as to the validity and enforceability of the patents are plainly without evidentiary support or legal merit.

(1) *Alleged Misappropriation of Inventions From UC*

54. BTG alleges that Genentech should have disclosed to the Patent Office during the prosecution of the applications for the '980 and '832 patents that Genentech misappropriated the inventions of the patents from UC. BTG introduced into the record certain testimony of UC scientist Howard Goodman from the related ITC Proceeding in an effort to establish that Genentech misappropriated the inventions of the '980 and '832 patents from UC. (Tr. 833, Statement of Counsel; Pl. Ex. S). This court finds that this evidence neither establishes that Genentech misappropriated the inventions of the '980 and '832 patents from UC (Tr. 862-863) nor does it establish that the inventions of the '980 and '832 patents were obvious over prior art of Dr. Goodman and his group of UC scientists. To the contrary, this court finds that Dr. Goodman's testimony was at best inconclusive and entitled to no weight. (Tr. 862). For example, Dr. Goodman could not [ ] (Tr. 820-822). He did not provide any probative testimony in support of the allegation that [ ] (Tr. 862-863).

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sibly relied upon by BTG is the Goodman work, which was discussed at length during the '832 and '980 prosecution. Raising the same prior art considered by the Patent Office does not carry BTG's burden of proof. *Custom Accessories, Inc.* v. *Jeffrey-Allen Industries, Inc.*, 807 F.2d 955 (Fed. Cir. 1986) (The burden of proving a patent claims unpatentability is heavier when the patent received a PTO reissue or reexamination in light of the same prior art presented to the district court).

(2) *BTG'S Allegations On Inventorship*

55. Equally unavailing is BTG's contention (set forth in its Memorandum in Opposition to Genentech's preliminary injunction motion) that Dr. Boyer, one of Genentech's founders, was the true inventor. This court finds that BTG has presented no evidence in support of its allegation that Dr. Boyer, rather than Dr.'s Goeddel and Heyneker, was the inventor of the '980 and '932 patents.

(3) *The Secondary Considerations Support Validity*

56. In determining the issue of a patent's validity, the court must consider the "objective evidence of non-obviousness" or "secondary considerations" when presented by the patent holder. *Glaverbel Societe Anonyme* v. *Northlake Marketing & Supply, Inc.*, 45 F.3d 1550, 1555 (Fed. Cir. 1995).

57. The criteria that have emerged for these secondary considerations include: (1) the commercial success of the products covered by the patent (*Simmons Fastener Corp.* v. *Illinois Tool Works, Inc.*, 739 F.2d 1573, 1575, 1576 (Fed. Cir. 1984), *cert. denied,* 471 U.S. 1065 (1985) ("[T]he evidence of secondary considerations in this case, particularly commercial success, is extremely strong, and is entitled to great weight."); *In re Sernaker*, 702 F.2d 989, 997 (Fed. Cir. 1983) (concurring opinion)); (2) long felt need in the art satisfied by the invention in the patent (*Stratoflex,* 713 F.2d at 1540; *In re Mahurkar Patent Litigation,* 831 F. Supp. 1354, 1378 (N.D. Ill. 1993) ("The existence of an enduring, unmet need is strong evidence that the invention is novel, not obvious, and not anticipated."); (3) failure of others to make the invention (*Minnesota Mining and Manufacturing Co.,* 976 F.2d at 1575); and (4) copying the invention by others in the field (*American Medical Systems, Inc.* v. *Medical Engineering Corp.*, 794 F. Supp. 1370, 1385-86 (E.D. Wis. 1992), *aff'd in part, rev'd in part,* 6 F.3d 1523 (Fed. Cir. 1993), *cert. denied,* U.S. ___, 114 S. Ct. 1647 (1994)).

(a) *Commercial Success*

58. Genentech's development and ultimate sale of its recombinantly produced hGH products pursuant to the processes of the '980 and '832 patents has resulted in extraordinary "commercial success." Genentech's hGH products, Protropin® (approved in 1985) and Nutropin® (approved in 1994) are both manufactured in accordance with the '980 patent. (Tr. 92-94, Falkinham) and are being marketed for the treatment of growth hormone deficiency in children. (Tr. 126, Matlock; Tr. 319, Whiting). Genentech's U.S. gross sales of hGH have steadily increased over the years from approximately $43.5 million in 1986 to $185.1 million in 1991 and $225.4 million in 1994. (Tr. 494, Whiting; Def. Exs. 106 and 107). The products of the '980 patent are indisputable commercial successes.

(b) *Long Felt Need*

59. A long felt need for the artificial growth hormone existed prior to the introduction of Genentech's recombinantly produced hGH products because prior to Genentech's inventions, hGH from natural sources was in short supply and was unavailable to treat all children who needed the treatment. (Tr. 287-289, Blizzard).

(c) *Failure of Others*

60. The inventions of the '980 and '832 patents are underscored by the failure of others to develop a viable process for the production of hGH. At the time Goeddel and Heyneker filed the application for the '832 and '980 patents, scientists at the University of California (led by Dr. Goodman) had failed to obtain an hGH coding sequence from which hGH could be produced. Indeed, up to almost a year after the filing of the application for the '980 patent, Dr. Goodman and his group were unable to find a way to remove the leader sequence, even though he had succeeded in obtaining the entire human growth hormone gene with the leader sequence. (Def. Ex. 2, pp. 102-104, 116 and 119-120).

(d) *Copying the Invention by Others in the Field*

61. There is substantial evidence that BTG blatantly copied the inventions of the '980 and '832 patents. The evidence establishes that BTG's plasmid which is used to produce its hGH product, [ ] is named for [ ] a BTG scientist who worked under the direction of Dr. Marian Gorecki. (Tr. 428, Gorecki). During cross-examination, Dr. Gorecki admitted that prior to beginning work on the construction of BTG's expression plasmid, [ ] read and were familiar with the *Nature* paper, authored and published by Goeddel and Heyneker in October 1979. (Def. Ex. 50). *Nature* describes the preferred embodiments of the '980 and '832 patents, including the utilization of a quasi-synthetic gene in the construction of a recombinant cloning vehicle capable of expressing hGH in bacteria. (Tr. 429-433, Gorecki). Dr. Gorecki admitted using *Nature* in preparing [ ] (Tr. 431-432, Gorecki). Moreover, the evidence establishes that in [ ] recording BTG's strategy for constructing [ ] quoted verbatim language from *Nature*. (Tr. 433-435, Gorecki). Thus, this court finds that in developing its strategy for producing hGH, BTG copied directly from *Nature* and thereby copied the preferred embodiment of the '980 and '832 patents.

62. This court finds that the imitation of Genentech's work by BTG forms an important indicium of non-obviousness.

63. Thus, this court concludes that the litany of secondary considerations present here create an overwhelming case for its finding that Genentech is likely to succeed on the issue of validity of the '980 and '832 patents.

IV. *IRREPARABLE HARM*

A. *Genentech Will Suffer Irreparable Harm To Its Goodwill and Reputation Among Its Customers, Including Pediatric Endocrinologists and Others, If BTG Is Permitted To Enter The Market and Is Subsequently Enjoined*

(1) *Pediatric Endocrinology*

64. Endocrinology is the study of the glands of internal secretion and, in particular, hormones produced by internal organs. (Tr. 286, Blizzard). Pediatric endocrinologists treat children who have thyroid disease, diabetes, sex gland disorders, and growth hormone deficiency, and a major part of their practice is referrals of children who have short stature. (Tr. 282, 286, Blizzard).

(2) *The Development of the Growth Hormone Market In the United States*

65. Prior to Genentech's first United States clinical trials for recombinant human growth hormone, which began in 1981 (Tr. 289, Blizzard), the only known treatment for growth hormone deficiency in children was growth hormone extracted from the pituitary glands of cadavers. (Tr. 287, Blizzard). There was never an adequate supply of pituitary hGH to treat all patients who needed it and even those patients who received treatment could not be given an adequate dose. (Tr. 287-288, Blizzard). Indeed, it took 365 pituitaries to treat one patient for one year. (Tr. 287, Blizzard). Even when a commercial distributor of pituitary derived hGH came onto the market in the United States in or about 1977, there remained a substantial shortage. (Tr. 288, Blizzard).

66. In or about 1984, two patients who had been treated with pituitary-derived hGH died from Creutzfeldt-Jacob disease, a neurologic disorder which usually occurs in elderly people. (Tr. 289, Blizzard). As a result, pituitary growth hormone was taken off the market in the United States in March 1985. (Tr. 289, Blizzard). When pituitary derived growth hor-

mone was taken off the market, Genentech's recombinant human growth hormone had been used in clinical trials, but had not been approved by the FDA for general use (Tr. 289, Blizzard).

67. In October 1985, the FDA approved Genentech's Protropin® (met-hGH) human growth hormone product and granted it Orphan Drug Status. (Tr. 289, Blizzard).

(3) *Genentech's Efforts to Build Goodwill*

68. Genentech sponsors a number of programs to build goodwill among physicians. These include the National Cooperative Growth Study ("NCGS"), its Uninsured Patient Program, a reimbursement support program and other programs involving education for patients and parents involved in growth hormone therapy. (Tr. 125, Matlock). NCGS is a study which Genentech initially instituted at the behest of the FDA which required Genentech to follow approximately 500 patients that had been involved in clinical trials of Protropin® for four to five years following the FDA's approval of Protropin® in 1985. (Tr. 126, Matlock). The program became such a valuable resource for pediatric endocrinologists that it was expanded to include all patients treated with Genentech's hGH. (Tr. 125-126, Matlock; Tr. 290-291, Blizzard). Because there are approximately 50,000 patient years of data in the NCGS data base (Tr. 126, Matlock), it supplies a wealth of information to pediatric endocrinologists who receive its various reports. (Tr. 290-291, Blizzard; Def. Exs. 95, 96, 97). Genentech pays the cost of NCGS, [ ] (Tr. 131, Matlock).

69. Pursuant to Genentech's uninsured patients program, any patient who requires any Genentech product and cannot afford it will be given the product at no cost. (Tr. 131, Matlock). Since 1985, Genentech has given away at least [ ] (Tr. 131, Matlock). [ ] Genentech's reimbursement assistance program assists patients and physicians through the process of securing reimbursement for the cost of growth hormone treatment from insurance companies. (Tr. 131-132, Matlock). Genentech also has developed goodwill by providing a

wide range of educational materials to patients and their parents on growth hormone therapy. (Tr. 132, Matlock).

(4) *The Administration Of Recombinant Human Growth Hormone To Children*

70. Recombinant hGH is administered daily by injections which are usually given by the parents of the children who are being treated. (Tr. 291, Blizzard). The process of reconstituting the drug which is packaged in powder hGH into injectable form is complex and involves many steps. (Tr. 291, Blizzard, Def. Ex. 98 E; Def. Ex. 98A). The prescribing physician is responsible for instructing patients in how to administer hGH therapy, but often nurse practitioners do the actual instructing. (Tr. 292, Blizzard). For some families, particularly those who are less sophisticated or educated, it has been very difficult to learn this process and, in some cases, children receive treatment from a visiting nurse or in visits to a health department. (Tr. 291, 313, Blizzard). Due to differences among the available hGH products, patients who switch from one product to another will require additional instruction from their doctors and/or nurses. (Tr. 297-302, Blizzard).

71. A significant percentage of children on growth hormone therapy (estimated by Dr. Blizzard at 20-25%) fail to comply with some aspects of their treatment regimen, resulting in poor response to therapy. (Tr. 300-302, Blizzard). One of the primary ways to avoid compliance problems is to avoid switching to different drugs (Tr. 302, Blizzard). Doctors in the United States have been strongly reluctant to switch to a different growth hormone product during the course of treatment. (Tr. 297-302, 305-306, Blizzard; 148, Matlock). Thus, for example, most doctors who began to treat patients with Protropin®, Genentech's met-hGH product, continued to use Protropin® for those patients even after Lilly's and Genentech's met-less hGH became available. (Tr. 297, Blizzard).

72. Dr. Blizzard expressed the opinion that if BTG is allowed to sell its hGH product in the U.S. and, then, after two years, BTG is taken off the market by reason of an

injunction obtained at Genentech's request, patients treated with BTG's product during that time period would become anxious regarding the forced change of drugs. Many would not remain in compliance with the treatment regimen. (Tr. 288-302, Blizzard). Dr. Blizzard based his testimony, in part, on his experience in the 1960's with situations in which patients were required to switch among three formulations of pituitary derived human growth hormone and experienced anxiety and compliance problems. (Tr. 298-299, Blizzard). Dr. Blizzard testified that the same or similar problems are likely to be encountered by patients who would be required to switch from BTG's product to another hGH product in the event that BTG's product were put on the market and then enjoined. (Tr. 302 -303, Blizzard). Dr. Blizzard further expressed the concern that if BTG is allowed to enter the market and is subsequently enjoined, [ ]

73. Bonnie Susan Matlock, Genentech's Director of Marketing, Planning and Development, who maintains regular contacts with the pediatric endocrinology community, provided substantial and credible evidence that Genentech's goodwill would be irreparably damaged in the event that BTG were allowed to enter the market for a period of two years, and were then enjoined following trial in this case. [ ] presented no evidence that would in any way contradict the evidence submitted by Dr. Blizzard and Ms. Matlock on this point.

74. It would be upsetting for children treated with hGH and their parents, having learned one complex process of administration, to be required to relearn another process of administration, and that switching brands during the course of long-term therapy would impose a burden on them, particularly on parents and patients who had originally found it difficult to learn the administration process. (*Id.*).

75. If BTG is enjoined after two or more years on the market, Genentech's goodwill with doctors and patients will be damaged irreparably. Physicians who had been using the BTG product would have to explain to their patients (and

their parents) why the hGH they had been receiving for some period of time is no longer available to them. (*Id.*). Many physicians, parents and children are likely to be angry and resentful against Genentech because of Genentech's role in taking BTG's product off the market.

76. BTG has stated that, if it is enjoined, it would provide free hGH to patients who were already using its product, in order to avoid forcing them to switch drugs. (Tr. 653-656, Fass). Such a solution, however, would be contrary to fundamental precepts of the patent law, since it would allow BTG to continue infringing Genentech's patents for a period of several years in effect to seed the market so that BTG will still be actively in the market when the patents expire. *BIC Leisure Products, Inc. and Wendglider Fred Ostermann, GmbH* v. *Windsurfing International, Inc.* 687 F.Supp 134, 137-138 (S.D.N.Y. 1988); *Amsted Industries Incorporated* v. *National Castings, Inc.*, 16 U.S.P.Q. 2d 1737, 1753 (N.D. Ill. 1990); *TP Orthodontics Inc.* v. *Professional Pioneers Inc.*, 20 U.S.P.Q.2d 1017, 1023 (E.D. Wis. 1991). Indeed, BTG could use such free goods to continue its relationships with pediatric endocrinologists and patients until Genentech's patents expire, and would thus gain a marketing advantage from its infringement. Moreover, such a program would be impractical and difficult to police. The only clear and certain way to avoid requiring patients to switch is by enjoining BTG from bringing its product to market until after a full trial on the merits.

B. *Genentech Will Suffer Irreparable Harm If BTG Is Allowed To Enter The Market Because It Will Lose Revenues* [ ]

(1) *The Market For Human Growth Hormone*

77. When Genentech's Protropin® hGH product was approved in 1985, Genentech had 100% of the United States hGH market (Tr. 153, Matlock) a situation which continued until March 1987 when Lilly entered the market with its Humatrope® hGH product. Since that time, Lilly and Genen-

tech have been the only competitors in that market. (*Id.*; Tr. 153, 174 Matlock). [ ]

78. In late 1993, Genentech's met-less hGH product, Nutropin®, was approved by the FDA for treatment of chronic renal insufficiency and, in March 1994, it was approved by the FDA for growth hormone deficiency. (Tr. 150-151, Matlock). Because Genentech's met-less hGH product, Nutropin®, first entered the market in 1994 and because of the reluctance of doctors to switch products during their patients' course of treatment, [ ] There are not separate markets for met-less hGH and met hGH. From a medical and clinical point of view, Protropin®, Humatrope and Nutropin® are viewed as equivalent products which are equally safe and effective. They compete against each other in the market place. (Tr. 293, Blizzard; Tr. 173, Matlock).

79. The price of human growth hormone in the United States market has remained stable and has not increased since 1985. (Tr. 147, Matlock). [ ] the price for hGH has remained in equilibrium at $35 per milligram. (Tr. 520, Fass; Tr. 146-147, Matlock).

80. The number of physicians who prescribe hGH is relatively small (Tr. 121-122, Matlock). Those physicians do not always have control over which drug product to prescribe because managed care organizations, health maintenance organizations and hospital pharmacies often dictate which products doctors may use. (Tr. 121-122, Matlock; Tr. 306-307, Blizzard). [ ] BTG's profit margin on hGH is approximately [ ] (Def. Ex. 92; Tr. 484, Fass). For these reasons, the market for hGH is particularly subject to disruption and price erosion. Goodwill built in that market is uniquely vulnerable.

(2) *Genentech's Commitment to Research and Development*

81. Since its inception in 1976, Genentech has expended nearly $2 billion dollars in research and development, [ ] (Tr. 322-323, Whiting). Between 1976 and the end of 1994

[ ] Research and development is an integral component of Genentech's corporate mission—the development of break-through pharmaceutical products that meet critical, previously unfulfilled medical needs. (Tr. 323, Whiting). Research on such break-through products that utilize new technology is inherently expensive and costly, with a high risk of failure. (Tr. 323, Whiting)

82. At Genentech, scientists are encouraged to engage in so-called curiosity projects, [ ] (Tr. 321-322, Whiting). Genentech has discovered products and potential products through such projects, the most notable example of which is Pulmozyme. (Tr. 321-322; Whiting).

83. [ ]

(3) *BTG's Projected Market Share In the hGH Market, Price Erosion In the Market and Genentech's Loss of Funds Available For Research And Development*

84. According to BTG's President, Dr. Sim Fass, if BTG is permitted to enter the United States market, it expects to achieve a market share of approximately [ ] during its first year on the market. (Tr. 518, 570 Fass). In particular, BTG expects to obtain between [ ] of the approximately [ ] new patients. (Tr. 518, Fass). BTG expects to continue to obtain 20% to 25% of new patients in its second and third years on the market. (Tr. 570, Fass). In addition, BTG expects to obtain [ ] of the existing patients who are being treated with Lilly's Humatrope product and Genentech's Nutropin® product. (Tr. 570, Fass). BTG expects that it will obtain [ ] million in revenues from hGH sales in the United States during its first 12 months on the market. (Def. Ex. 88, Tr. 139-140, Matlock; Tr. 659, Fass).

85. [ ]

86. Accepting as true BTG's projected sales of [ ] per year, which is a conservative assumption, assuming price erosion of 10%, and assuming that BTG is on the market for only one quarter of 1995, [ ] Assuming higher price erosion of

20%, an assumption that is not unreasonable in light of BTG's prior public statements that it would offer discounts of 20% to 40%, [ ] BTG has not challenged the basis for these projections except insofar as it denies that it intends to engage in price competition, an assertion by BTG which this Court rejects for the reasons described below. [ ]

87. BTG asserts that its sales will reduce Genentech's revenue only [ ] (Tr. 500, Fass), but this is based on several faulty assumptions: BTG assumes that it will capture [ ] of Genentech's existing customers [ ] by persuading them to switch to BTG's product, but that BTG [ ] patients, and [ ] patients that would otherwise use Genentech's products. These assumptions are contrary to the record at least for the following reasons:

(a) Historically, Genentech's Protropin® product, which is a met-hGH formulation, has competed with Lilly's Humatrope product, which is a met-less formulation, [ ] Thus, BTG's assumption that [ ] product in the same market for either new or pre-existing patients is inappropriate and misleading;

(b) BTG's assertion in this case that it does not expect [ ] is the exact opposite of the position which BTG maintained as late as 1993 (Tr. 597, Fass) when BTG's primary marketing objective [ ] product, to switch to BTG's [ ] product. (Tr. 597, Fass); and

(c) If BTG's [ ] assumption were accurate, it would mean that [ ] and that all of BTG's new patients would come out of Lilly's share, [ ] Such a result is unsupported by any credible testimony. Thus the Court finds it reasonable to assume that BTG's patients would come from Genentech and Lilly in proportion to their present market share.

88. BTG's assertion that its entry onto the market will decrease Genentech's revenues by [ ] is also based in substantial part on the assumption and representation by BTG's President, Dr. Fass, that BTG [ ] an assumption and representation which is highly suspect for the following reasons:

(a) Until this hearing, BTG officials repeatedly and clearly stated that if BTG is allowed to enter the United States hGH market, BTG will [ ] Thus, for example, in responses to questions of the United States Subcommittee On the Judiciary which BTG's Dr. Fass provided by letter to Senator Howard M. Metzenbaum dated August 13, 1991 (Def. Ex. 116), BTG stated:

> "If Bio-Technology Corp.'s hGH were to be approved, the Company would launch the product at a major discount between 20%-40% (!) at every dosage level, to Lilly's and Genentech's price levels."

(Def. Ex. 116; Tr. 530-531, 558-559, Fass). In a 1992 interview with Medical Advertising News, Dr. Fass again stated that BTG had "made a commitment to cut the price not only to benefit patients, but to allow us as well to capture market share". (Tr. 566-567, Fass; Def. Ex. 91). In a May 10, 1995 news article in Bioworld Today, BTG's Director of Corporate Information, Leah Berkovitz, was quoted as stating that "[t]here is room for some price adjustment . . . it's a high-cost drug with a high profit margin and there's room for some adjustment". (Def. Ex. 92; Tr. 594-595, Fass). Dr. Fass also testified in the hearing before this Court that, in his view, the current price of hGH was at an unconscionably high level for Genentech. (Tr. 512, Fass). Moreover, several [ ] for BTG's Bio-Tropin™ product advised BTG that BTG [ ] (Tr. 513-516, 537-539, 557, 587-590; Def. Ex. 131; Def. Ex. 132).

(b) BTG asserts that it will avoid the need [ ] by offering [ ] administration system (Tr. 657, Fass), and by offering its product [ ] (Tr. 474, Fass). However, both of these strategies are speculative. BTG has not yet even signed a contract to obtain the rights to [ ] (Tr. 661-662, Fass). The FDA has not yet approved use of the [ ] human growth hormone (Tr. 662, Fass), and BTG cannot be certain when, if ever, it would be able to use [ ] in connection with its Bio-Tropin™ hGH product.

(c) Moreover, BTG did not present any evidence to establish that [ ] would be preferred by patients and doctors, or

is [ ] for patients or otherwise advantageous when compared to [ ] utilized by Genentech and Lilly. (Tr. 642, Fass).[2] Dr. Fass' hearsay description of a European study is deserving of no evidentiary weight. Dr. Fass never actually saw or read the study and BTG did not bring the study to Court or attempt to introduce it into evidence. (Tr. 640, Fass). Dr. Fass admitted, moreover, that [ ] (Tr. 644, Fass). The only credible evidence in the record concerning patient acceptance of [ ] is a published European study in which the authors concluded that, "Insulin therapy using [ ] was not well accepted by our patients, irrespective of the presence or absence of [ ], that there was "poor acceptance" of [ ] and that [ ] patients experienced less immediate pain, but more delayed pain and more bleeding with [ ] (Def. Ex. 141, p. 138).

(d) BTG's assertion that it will be able to differentiate its product by using it [ ] for treatment of children with Turner Syndrome (Tr. 474, Fass) is also highly questionable. To date, [ ] has been approved by the FDA for treatment of children with Turner Syndrome. (Tr. 475, 523, Fass). BTG has not yet filed its New Drug Application for [ ] and does not expect to do so until late 1995, and does not expect to obtain FDA approval before "the end of 1996". (Tr. 647, Fass). Moreover, [ ] has expired (Tr. 645, Fass) and anyone, including Genentech, could [ ] Indeed, the potential use [ ] has been known for 20 years. (Tr. 646, 647, Fass). Genentech used [ ] in a major study of treatment for [ ] and published reports in 1986 about this study, a study that is substantially similar to the clinical trials that BTG has conducted on this subject. (Tr. 646-648, Fass; Def. Ex. 120, Def. Ex. 121). Based on the foregoing, this court has substantial reason to doubt the credibility of BTG's claim that it will be able to utilize [ ] product to differentiate its hGH product from those of its competitors.

(e) Equally unconvincing is BTG's assertion that it cannot afford to [ ] which it expended to defend itself against

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[2] [ ]

Genentech's claims in the ITC Proceeding. (Tr. 506, Fass). Even accepting BTG's projections, if permitted to enter the hGH market in the United States, BTG would have sales of [ ] in the next three years, [ ] of which would be profit. (Def. Ex. 130, Tr. 570-578, Fass). This would be more than sufficient to cover the [ ] which BTG purportedly expended in the ITC Proceeding, and thus the Court rejects BTG's assertion that the need to recoup those expenditures would prevent it from [ ]

89. Genentech presented credible evidence that if BTG entered the United States hGH market, it is likely to [ ] Genentech's Director of Marketing, Planning and Distribution, Bonnie Matlock, has extensive experience in the United States market place and as part of her duties collects voluminous information regarding Genentech's actual and potential competitors. (Tr. 117-121, Matlock). She testified that, because BTG does not have the capacity to compete on the basis of service or product differentiation, [ ][3] by [ ] (Tr. 140, 142-143, Matlock). This court finds Ms. Matlock's testimony to be credible and further finds that, for the reasons set forth above, BTG has not established that it can [ ]

90. [ ]

(4) *If BTG Is Permitted To Enter The Market, Genentech Will Irreparably Lose Goodwill, Customers, and Market Share and its Research and Development Programs Will Be Irreparably Harmed*

91. A party who makes a clear or strong showing of patent validity and infringement is entitled to a presumption of irreparable harm and need not make any additional affirmative factual showing to support that presumption. *Smith Int'l, Inc.* v. *Hughes Tool Co.*, 718 F.2d 1573, 1581 (Fed. Cir.), *cert.*

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[3] In a recent publication, Bill Pursley, BTG's Vice President of Marketing and Commercialization, estimated that BTG would capture $20 million of sales during the first 12 months of U.S. sales. (Def. Ex. 88). Mr. Pursley is a former employee of Genentech and has extensive experience in the hGH market. [ ]

denied, 464 U.S. 996 (1983), *cert. denied*, 474 U.S. 827 (1985). Having found that Genentech has proven a strong likelihood of success on the merits, this court finds that there is a presumption of irreparable harm.

92. The loss of goodwill ordinarily constitutes irreparable harm because it is impossible to quantify and cannot be adequately rectified by money damages. *Gateway Eastern Railway Co.* v. *Terminal Railroad Assoc. of St. Louis*, 35 F.3d 1134, 1140 (7th Cir. 1994); *Ideal Toy Corp.* v. *Chinese Arts & Crafts, Inc.*, 530 F. Supp. 375, 380 (S.D.N.Y. 1981) (Motley, J.). Moreover, the loss of goodwill and potential revenue caused by an infringer's actions during the pendency of litigation may constitute irreparable harm to the patent holder. *American Home Products Corp.* v. *Johnson & Johnson Corp.*, 22 U.S.P.Q. 2d 1561, 1567, 1991 WL 255825 (E.D.Pa. 1991).

93. The Federal Circuit has recognized that expected decreases in funds available for research and development resulting from anticipated loss of revenues and market share constitute irreparable harm:

> "Without the right to obtain an injunction, the right to exclude granted to the patentee would have only a fraction of the value it was intended to have, and would no longer be as *great an incentive to engage in the toils of scientific and technological research.*"

Smith Int'l Inc., 718 F.2d at 1577-78, (emphasis added) (reversing denial of preliminary injunction); *Hybritech*, 849 F.2d at 1456 (effects on research if interim relief is not granted are a factor to be considered in determining irreparable harm). The court finds that BTG's entry into the U.S. market will cause irreparable harm to Genentech by decreasing the funds available to it for research and development.

94. There can be no assurance that damages could compensate Genentech for its losses of customers and market share. (Tr. 146-148, Matlock.). Likewise, if BTG enters the market and there is substantial price erosion, [ ] At the end of 1994, BTG had cash and marketable securities of [ ] (Tr.

328, Whiting; 484, Fass; Def. Ex. 108), and even with its profits from sales of its Bio-Tropin™ product in the United States, there is a substantial risk that BTG would not have the resources to fully compensate Genentech for its damages in the event BTG was allowed to enter the market and was subsequently enjoined. BTG stated it had plans [ ] (Tr. 485, 621, Fass).

95. The Federal Circuit has held that infringement may have market effects, such as loss of market share, never fully compensable by damages and, as such, may constitute irreparable harm. *Atlas Powder Co.* v. *Ireco Chemicals*, 773 F.2d 1230, 1233 (Fed. Cir. 1985); *Hybritech*, 849 F.2d at 1457; *see also Maitland Co., Inc.* v. *Terra First, Inc.*, 33 U.S.P.Q. 2d 1882, 1896 (D.S.C. 1994); *Critikon, Inc.* v. *Becton Dickinson Vascular Access, Inc.*, 28 U.S.P.Q. 2d 1362, 1370, 1993 WL 330532 (D.Del. 1993); *Henkel Corp.* v. *Coral, Inc.*, 754 F. Supp. 1280 (N.D.Ill. 1990), *aff'd*, 945 F.2d 416 (Fed. Cir. 1991) (finding that damage to market share and reputation are not measurable strictly in monetary terms). Indeed, the Federal Circuit has recognized that the patent statute provides monetary relief for infringement but that a preliminary injunction maintaining the *status quo* is paramount:

> "it does not follow that a money award is also the sole remedy against future infringement. The patent statute further provides injunctive relief to preserve the legal interests of the parties against future infringement which may have market effects never fully compensable in money. If monetary relief were the sole relief afforded by the patent statute then injunctions would be unnecessary and infringers could become compulsory licensees for as long as the litigation lasts."

Atlas Powder, 773 F.2d at 1233.

96. BTG argues that Genentech cannot show irreparable harm because Genentech has [ ] Lilly. However, Genentech [ ] Lilly only after years of protracted litigation. Even now only Genentech and Lilly are in the market, and new market

entrants would substantially disrupt this unique market of 700 pediatric endocrinologists. In such circumstances, as a matter of law, Genentech's [ ] to Lilly does not negate irreparable harm. *E.I. Du Pont de Nemours & Co.* v. *Polaroid Graphics Imaging, Inc.*, 706 F. Supp. 1135, 1144-1145 (D. Del. 1989) (finding irreparable harm where patentee had licensed the invention, even though patentee did not practice the invention); *Johnson & Johnson Consumer Products, Inc.* v. *Ormco Corp.*, 1988 WL 155634 (D. Del. 1988); *Vulcan International, Inc.* v. *Jerr-Dan Corp.*, 31 U.S.P.Q. 2d 1911 (N.D. Miss. 1994).

V. THE BALANCE OF EQUITIES TIPS DECIDEDLY IN GENENTECH'S FAVOR

97. Genentech's pioneering '980 and '832 patents, and its vast expenditures on research and development created recombinant hGH technology and resulted in the development of the United States market for DNA. In contrast, BTG copied the inventions of Genentech's patents, expending substantially less in the research and development of its hGH product.

98. It is vital for Genentech to maintain its research and development efforts if it is to continue to develop breakthrough pharmaceutical products. BTG asserts that its research efforts on other products will be hampered if it is prevented from marketing and selling hGH in the United States. (Tr. 476-477, Fass). It would be unfair and inequitable for BTG to be allowed to utilize revenues from its acts of infringement to support its research and development activities, while at the same time [ ]

99. Genentech will suffer [ ] irreparable loss of goodwill, market share, and customers in the event BTG is permitted to enter the market now, and is later enjoined. In addition, BTG's entry into the market place [ ] Even if BTG is enjoined following trial on the merits, [ ]

100. By obtaining the '980 and '832 patents, which are presumptively valid, Genentech thus obtained the right to

exclude others from making a product which infringes the patents. Its patent rights under the '980 patent expire in 2003 and its patent rights under the '832 patent expire in 1999. Yet if BTG is permitted to enter the market, and if it takes two or more years for this case to be tried, and an additional year or so for the appeals process, Genentech would be left with only 5 years or less of remaining patent protection under the '980 patent, and one year or less of remaining patent protection under the '832 patent. *See, H.H. Robertson Co.*, 820 F.2d at 391 (granting preliminary injunction where "patent does not have many years left"); *Sensormatic Electronic Corp.* v. *Minnesota Mining & Mfg. Co.*, 10 U.S.P.Q.2d 1467 (SD. Fla. 1988) (granting preliminary injunction where patent has only 2 years left that were "critical" to the future of the industry).

101. In contrast, BTG has not yet entered into the United States market and will suffer no harm from a preliminary injunction, which would merely maintain the *status quo*. As the Federal Circuit has recognized, "[w]hen the movant has shown the likelihood that the acts complained of are unlawful, the preliminary injunction 'preserves the status quo if it prevents future trespass'. . ." *H.H. Robertson*, 820 F.2d at 390-391 (preliminary injunction affirmed). *See also*, *Atlas Powder*, 773 F.2d at 1234 (upholding a preliminary injunction where 66% of a party's total sales were enjoined and 200 employees would be laid off, even though the patent would expire within the year).

102. BTG's argument that Genentech comes to this court with unclean hands and should be penalized here because of its purported discovery abuses in the ITC Proceeding is not well taken. Different rights and claims were at issue in the ITC Proceeding, and Genentech's alleged discovery misconduct in the ITC Proceeding does not relate to rights at issue in this case.[4] For purposes of relevance to this case, any pur-

[4] The "defense of unclean hands applies only with respect to the right in suit." *Warner Bros., Inc.* v. *Gay Toys, Inc.*, 724 F.2d 327, 334 (2d Cir. 1983) (finding no unclean hands as to plaintiff's unfair competition claim even though plaintiff threatened defendant with prosecution on a

ported discovery abuse was cured by Genentech in July 1994 when Genentech produced the so-called GLP documents to BTG. BTG has had these documents for 11 months. Thus, there is no reason to believe that it cannot receive a fair adjudication of the issues on this motion and at trial. Genentech's sanction in the ITC was based on findings of an administrative agency that will soon be reviewed in the Federal Circuit. However, even if there were no appeal pending in the Federal Circuit, it would be inappropriate for this Court to place a limitation on Genentech's procedural and substantive rights in this proceeding based on purported misconduct as to which Genentech has already suffered a severe sanction.

103. BTG also asserted that Genentech has unclean hands because it allegedly misappropriated the inventions of the '980 and '832 patents from a group of UC inventors led by UC scientist Dr. Howard Goodman. (Tr. 833, Statement of Counsel). The sole evidence offered by BTG in support of this assertion was testimony from Dr. Goodman's deposition in the ITC Proceeding, (Tr. 819-862) which the court has rejected earlier herein. Thus, the Court finds that BTG has offered no evidence in support of its misappropriation theory.

104. BTG argues that the court erred during the hearing when it refused to admit into the record certain so-called "GLP" documents which were among the group of documents which Genentech unintentionally produced to the parties in another patent infringement litigation (the "MDL Litigation"). *See, In Re Recombinant DNA Technology Patent and Contract Litigation.* 30 U.S.P.Q. 2d 1881, 1906 (S.D. Ind. 1994) (Dillin, J.). On May 31, 1995, the court signed an Order, agreed to by Genentech and BTG, for purposes of facilitating

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false trademark claim which had slight factual support); *Mallis* v. *Bankers Trust Co.*, 615 F.2d 68, 75 (2d Cir. 1980), *cert. denied*, 449 U.S. 1123 (1981) ("New York law ordinarily permits an unclean hands defense only when plaintiff's reprehensible conduct is 'directly related to the subject matter in litigation and the party seeking to invoke the [unclean hands] doctrine was injured by such conduct.'" (citing *Weiss v. Mayflower Doughnut Corp.*, 1 N.Y.2d 310, 316, 152 N.Y.S.2d 471, 474, 135 NE.2d 208, 210 (1956)).

the expeditious resolution of this motion without the need for the court to decide the complex issue of whether Genentech has waived its privilege as to the GLP documents. The court directed that the GLP documents could be submitted to the court *in camera* without waiver of Genentech's right to maintain its claim of privilege as to the documents and to object to their admissibility. (Order, May 31, 1995). During the hearing on Genentech's motion for a preliminary injunction, the court ruled that certain GLP documents which BTG attempted to introduce into the record were privileged and inadmissible for purposes of this hearing.

105. Because the court ruled that the GLP documents were privileged for purposes of the hearing on the motion for a preliminary injunction, the court did not decide during the hearing the issue of whether the GLP documents proffered by BTG would otherwise have been admissible, an issue which has been fully briefed by the parties. The court now finds that even if it were ultimately determined that Genentech waived any applicable privilege, the documents proffered by BTG are not admissible. BTG made no showing that the documents were adoptive or vicarious admissions by Genentech. At best, the privileged GLP documents offered by BTG are internal memoranda of Genentech's legal team discussing possible legal strategies and tactics. While they reflect the internal thought processes and deliberations of Genentech's lawyers, they do not reflect positions adopted by Genentech or by counsel on its behalf, nor do they reflect admissions by agents of Genentech. Instead, they are inadmissible hearsay. *See*, Rules 801(d)(2)(B), 801(d)(2)(d), Fed. R. Evid; *Headman* v. *Berman Leasing Co.*, 352 F. Supp. 211, 213-214 (E.D. Pa. 1972) (statement by attorney in telephone conversation with adversary attorney not admission binding on client since out-of-court statements are not recitations of client's position); *U.S.* v. *McKeon*, 738 F.2d 26 (2d Cir. 1984)(cautioning against liberally finding attorneys' out-of-court statements as admissions). If statements such as those described in the GLP documents proffered by BTG were admissible, every rejected suggestion by an attorney, consultant, or expert retained by a

party would be admissible under the hearsay rule, notwithstanding the fact that the party could not know what the statement would be before it was made. *See*, *Sanford* v. *Johns Mansville Sales Corp.*, 923 F.2d 1142, 1149-50 (5th Cir. 1991).

106. Moreover, after reviewing the GLP documents submitted by BTG *in camera*, the court has determined that none of the privileged information disclosed in the GLP documents submitted *in camera* by BTG is of material significance to the outcome of Genentech's motion and, therefore, that the ultimate resolution by the court of the legal issues relating to Genentech's claim of privilege as to the documents would not change or affect the ruling by the court on this motion.

107. BTG's argument based on the so-called "grandfather clause" of 35 U.S.C. § 271(g), is unavailing. Section 271(g) instructs a court to allow an entity which made commercial investments and substantial preparation *in the United States* to continue to use, sell or import its product "to the extent equitable" to protect that entity's commercial investment or business commenced in the United States prior to January 1, 1988. As explained below, the evidence presented by BTG did not establish that BTG engaged in substantial preparation for sale or use of hGH in the United States prior to 1988.

108. BTG showed that it raised [ ] from United States investors and debt financing prior to 1988. (Tr. 401, 405; Fass). However, Dr. Fass, admitted that these funds were raised in support of all of the various BTG products that were being developed, not merely for hGH. (Tr. 405-406, Fass). Moreover, the evidence established that substantial portions of these funds were utilized to construct BTG's plant in Israel where it manufactures its hGH product and its other products for worldwide sale. (Tr. 456-457). All of BTG's research and development expenditures relating to hGH were expended in Israel. (Tr. 532, Fass). The only expenditures prior to the 1988 effective date of § 271(g) that BTG's President cited as having been incurred by BTG in the United States were expenditures for preclinical animal studies (Tr. 532-533,

Fass), but Dr. Fass stated his belief, based upon a 1991 letter he sent to Senator Metzenbaum and without any other supporting contemporaneous documentation, that BTG expended $2.2 million in the United States for clinical trials prior to 1988. (Tr. 543-544, Fass).

109. Despite the court's direction that BTG submit documents to substantiate its claim of having expended $2.2 million for clinical trials conducted in the United States (Tr. 551-552), Dr. Fass purported to have located documents reflecting expenditures prior to 1988 of [ ] for clinical trials conducted in Israel. (Tr. 599, Fass).

110. To the contrary, the evidence in the record suggests that BTG did not expend any funds in the United States for clinical trials prior to at least 1991. In particular, BTG entered into an agreement with American Critical Care ("ACC") in 1986 pursuant to which ACC was granted an exclusive license to use and sell BTG's hGH product and had the obligation to conduct clinical studies and related regulatory activity to obtain FDA approval (at ACC's own costs) in exchange for payments to BTG. (Pl. Ex. LL; Tr. 406-407, 533, Fass). In 1986, DuPont bought ACC and thus became an assignee of the ACC agreement, and in September, 1987, Dupont filed a New Drug Application with the FDA for BTG's Bio-Tropin™ hGH product. (Tr. 407, 533-534, Fass).

111. BTG's President, Dr. Fass, admitted that ACC and Dupont took responsibility for paying for and completing the clinical trials and filing BTG's New Drug Application (Tr. 406-407, 533-534, Fass) but claimed, without documentary support, that BTG had begun the human clinical trial process and paid for half of the clinical trials which were conducted in the United States during 1986 - 1987. (Tr. 406-408, 598-599). Dr. Fass' statements concerning the extent of BTG's involvement in United States clinical trials are belied by BTG's filings with the Securities Exchange Commission ("SEC") and, indeed, when confronted with BTG's Annual Reports to Shareholders and SEC filings, Dr. Fass conceded that his recollection may have been wrong, that BTG's

involvement in clinical trials might have been limited to Israel, and that the entirety of United States clinical trials were conducted by ACC. (Tr. 603, Fass). In BTG's 1985 Annual Report, BTG stated, "[t]he company filed an investigational new drug (IND) application with the FDA in December 1985 for human growth hormone and in February 1986 began human clinical trials in conjunction with ACC" (Def. Ex. 136, p. 3), and that "Phase 1 testing in adults was completed satisfactorily in March 1986 in conjunction with ACC . . . The Phase 2 studies are underway". (Def. Ex. 136, p. 4). Likewise, BTG's 1985 Annual Report on Form 10-K reports that clinical trials were commenced in 1986 in conjunction with ACC (Tr. 613, Fass; Def. Ex. 139, p. 5), and that ACC "will bear the expenses incurred in connection with such clinical trials and regulatory approvals". (Tr. 615, Fass; Def. Ex. 139, p. 5).

112. Dr. Fass' testimony before this court concerning BTG's role in United States clinical trials was also contrary to his prior testimony in the ITC Proceeding in which Dr. Fass testified that the clinical trials were "done by ACC initially" (Tr. 608, Fass) and that it was DuPont's responsibility to conduct and pay for clinical trials in both the United States and Israel in coordination with BTG. (Tr. 609, Fass). In his ITC Testimony, Dr. Fass testified that BTG's role was limited to coordination among DuPont, clinical investigators and patients. (Tr. 609, Fass). Moreover, Dr. Fass admitted that Dupont quantified its expenditures for clinical trials as being $3,000,000 and that BTG's total costs for clinical trials were a very small percentage of the costs incurred by DuPont because ACC and later Dupont took over and absorbed the cost. (Tr. 610-612, Fass). Thus, Dr. Fass' assertion that BTG expended substantial sums in support of United States clinical trials is belied by the evidence and Dr. Fass' own admissions on cross-examination.

113. Moreover, even assuming that BTG incurred a small amount of expenses in the United States for clinical trials, the evidence establishes that the payments which BTG received

from ACC and DuPont more than offset any such expenditures by BTG and allowed BTG to fully recoup its investment in the United States prior to 1987. Thus, in 1986, ACC paid BTG $228,000 for hGH used in clinical trials and in 1987, Dupont paid BTG $149,000 for hGH used in clinical trials. (Tr. 604, Fass; Def. Ex. 138, p. 24). The court concludes that BTG cannot seek to invoke equity to recoup purported investments in the United States for which it was already paid by DuPont and ACC.

114. In 1991, BTG reacquired its rights to human growth hormone from DuPont including rights to the New Drug Application that had been filed by DuPont. (Tr. 454-455, Fass; Pl. Ex. MM). However, BTG's 1991 expenditures to reacquire rights to human growth hormone are irrelevant to the question of whether BTG is entitled to an equitable exemption under § 271(g). Only BTG's expenses prior to 1988 are relevant to that issue.

115. BTG is also asserting that it meets the "substantial preparation" criterion of the grandfather clause of § 271(g). To do so, BTG must show: (i) that it made substantial preparation *in the United States* prior to January 1, 1988 for the importation of hGH; and (ii) that it would be equitable for the protection of BTG's commercial investments made or business commenced "*in the United States*" to allow BTG to engage in unfettered importation now that it has received FDA approval to sell Bio-Tropin™. *See, Shamrock Technologies, Inc.* v. *Precision Micron Powders, Inc.*, 20 U.S.P.Q. 2d 1797, 1799 (E.D.N.Y. 1991).

116. The Court finds that BTG has failed to show that it made substantial preparation in the United States prior to 1988.

117. BTG further argues that it deserves an exemption under the grandfather clause because it raised substantial funds from United States investors prior to 1988. BTG does not dispute, however, that most of the funds which it raised from United States investors were expended outside of the United States. The grandfather clause permits the Court to

exempt BTG only to the extent equitable to protect *its commercial investments in the United States*. The "in the United States" language of the grandfather clause is a critical requirement and cannot be ignored. Changes to the grandfather clause made by Congress prior to its final enactment reveal the importance of the "in the United States" requirement. As originally proposed, the grandfather clause read:

> ". . . already in substantial and continuous commercial production on July 31, 1985, or for which commercial production was made before the date, to the extent equitable for the protection of investment made or business commenced before that date."

(*See*, S. 1543, 99th Conf. 1st Sess. Process Patent Amendment Action of 1985, Introduced July 31, 1985). During Senate hearings on this proposed subsection of the S. 1543 bill, it was argued that this grandfather clause was overbroad and should be either eliminated or narrowed so that "the phrase 'commercial production' and the reference later in the same sentence 'to investment made or business commenced' should be limited to the United States" (Process Patents, 1985, Hearing Before the Subcommittee on Judiciary, 99th Cong., 1st Sess. 57 (1985) (statement of Donald W. Bannon, President of Intellectual Property Owners, Inc.)).

118. Before enactment, Congress amended the grandfather clause to restrict investments to the United States. This intentional restriction of the grandfather clause to commercial investments made in the United States is entitled to significant weight. *See generally, Seatrain Shipbuilding Corp v. Shell Oil Co.*, 444 U.S. 572, 596 (1980). Therefore, BTG cannot invoke the grandfather clause by relying on its raising of capital from United States investors.

119. BTG finally argues that when it reacquired rights to human growth hormone from DuPont in 1991, it became a "successor in business" (as that term is used in the grandfather clause) to DuPont's purportedly substantial investments in the United States prior to 1988. The fatal flaw in that argument is that DuPont was merely a licensee of BTG which was

granted the right to market and sell BTG's infringing product in the United States and, therefore, in 1991, BTG did not succeed to DuPont's business but merely reacquired rights which it had licensed to DuPont. The legislative history of the grandfather clause makes clear that the phrase "successor in business" "does not include parties to whom the grandfathered infringer may license the goods; the phrase is meant only to allow the infringer who *sells his business* to pass on also its grandfathered status to the buyer of the business." (S. Rep. 100 - 83, at p. 59). Moreover, a successor in business must at least acquire a distinct line of the predecessor's business. *Drilling Well Contract, Inc.* v. *Dress Industries, Inc.*, 340 F.Supp. 1266, 1283 (S.D.Tex. 1970) (discussing successor in business in terms of 35 U.S.C. § 252, the patent statute on which the grandfather clause of § 271(g) was patterned). In 1991, clearly BTG did not acquire DuPont's business, but, rather, reacquired merely the rights to market its infringing product in the United States.

120. Even assuming for the sake of argument that the grandfather clause of § 271(g) is applicable to BTG, the court must still determine the extent to which it would be equitable to allow BTG to import its infringing product to recoup its investment in the United States. At this stage, BTG has not presented evidence sufficient to convince the court that it would be equitable to allow it to enter the United States market and thereby change the *status quo*. Indeed, it appears that BTG has fully recouped any United States investment which it may have made prior to 1988 in payments from American Care Corporation, DuPont, and in its worldwide hGH sales. Moreover, the evidence that BTG has copied Genentech's patents is a matter of equity against invoking the grandfather clause in BTG's favor.

121. BTG argues that this court should deny Genentech's motion for a preliminary injunction because it is likely to prevail on a defense of laches. The sole evidence which it offers in support of this defense is testimony and documentary evidence that in 1985 and 1986, Genentech was informed by

BTG that BTG had developed a human growth hormone product which BTG was importing into the United States for the purpose of conducting clinical trials. (Tr. 388 - 399, Fass, Pl. Ex. JJ, Pl. Ex. KK). BTG would have this court believe that Genentech should have brought suit soon after it learned this information in 1985 and 1986.

122. However, as a matter of law, prior to 1988 when § 271(g) became effective, BTG's importation of human growth hormone for any purpose, including clinical trials or sale to the public, could not have resulted in claims by Genentech against BTG for infringement of its process patents covering hGH, including the '980 and '832 patents. *See, e.g., In re Amtorg Trading Corp.*, 75 F.2d 826, 832 (C.C.P.A.), *cert. denied*, 296 U.S. 576 (1935). Thus, Genentech could not have had a patent infringement claim against BTG under the '980 and '832 patents prior to 1988. It is axiomatic that laches cannot attach where a cause of action has not arisen.

123. Even after the enactment of § 271(g) which became effective in 1988, the only information known to Genentech was that BTG was importing hGH for use in connection with clinical trials in support of its application for FDA approval. 35 U.S.C. § 271(e)(1) provides that it is not an act of infringement "to make, use or sell . . . for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use or sale of drugs . . .". Congress made clear in the legislative history of § 271(e) that it is not an act of infringement to import into the United States a product (which is made by a process patented in the United States) for use in the development and submission of information to the FDA (S. Rep. No. 83, 100th Cong. 1st Sess., 48, 59 (1987)). Thus, pursuant to § 271(e)(1), BTG's importations of its human growth hormone product into the United States for use in clinical trials reasonably related to its efforts to obtain FDA approval constituted non-infringing acts. Again, laches cannot attach where there is no cause of action.

124. BTG offers no evidence that Genentech became aware prior to 1993 that BTG had imported its human growth hormone for some purpose outside the scope of § 271(e)(1) (and thus, would have been infringing).

125. In early 1993, when Lilly's period of exclusivity was nearing an end, Genentech could reasonably have assumed that BTG was preparing to activate its application for FDA approval of Bio-Tropin™, previously placed on hold, and that BTG also was preparing to enter the market upon the expiration of Lilly's Orphan Drug status on March 8, 1994. Accordingly, on March 16, 1993, Genentech filed a complaint in the ITC alleging that BTG was planning to manufacture and import infringing human growth hormone for commercial sale and distribution in the United States beginning in March 1994. Even then, Genentech did not have any specific knowledge of infringement, but based its complaint on the reasonable belief that BTG was likely to begin importing hGH for commercial purposes not exempt under § 271(e)(1) in order to be ready to enter the market in March 1994.[5]

126. Even if there were any merit to BTG's laches defense, it would not bar Genentech from obtaining a preliminary injunction. In patent cases, the defense of laches bars relief only for damages accrued prior to the suit and would not necessarily bar injunctive relief. *Gasser Chair Company, Inc. v. Infanti Chair Mfg. Corp.*, slip op. Case No. 94-1282 (Fed. Cir., June 1, 1995).

127. BTG also argues that it would be inequitable to grant Genentech a preliminary injunction because Genentech never sought a preliminary injunction against Lilly. However, Genentech reached a settlement with Lilly only after years of

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[5] Unlike a United States district court, the ITC's jurisdiction ". . . is premised upon either an actual importation of goods or an imminent threat of importation of goods which would give rise to an 'unfair method of importation' or an 'unfair act' pursuant to Section 337." Barry D. Rein & John J. Normile, *Enforcement of Patent Rights When Confronted with Foreign and Domestic Infringement*, New York State Bar Journal, May/June 1995, at 61, n.4.

protracted patent and contract litigation, including litigation involving the patents in suit. [ ] as shown in the testimony of Stephen Raines, Genentech's Vice President, [ ]

128. In sum, this court finds that the balance of equities weigh decidedly in favor of Genentech.

VI. THE PUBLIC INTEREST FAVORS THE GRANTING OF A PRELIMINARY INJUNCTION

129. The Federal Circuit has held that public interest favors the grant of injunctions, including preliminary injunctions, to stop patent infringement. *Smith Int'l. Inc.*, 718 F.2d at 1578 ("Without the right to obtain an injunction, the right to exclude granted to the patentee would have only a fraction of the value it was intended to have . . ."). Indeed, the "protection of patents furthers a strong public policy . . . advanced by granting preliminary injunctive relief when it appears that, absent such relief, patent rights will be flagrantly violated". *H H. Robertson,* 820 F.2d at 391.

130. Moreover, the patent grant functions as a means of raising the expected return to be gained from basic research to overcome the researcher's risk. *Eli Lilly and Co.* v. *Premo Pharmaceutical Labs.*, 630 F.2d 120, 137 (3d Cir.), *cert. denied*, 449 U.S. 1014 (1980); *Ortho Pharmaceutical Corp.* v. *Smith,* 18 U.S.P.Q. 2d 1977, 1989 (E.D.Pa. 1990), *aff'd*, 959 F.2d 936 (Fed. Cir. 1992) ("The policy rationales behind the patent statutes generally apply with even greater strength in the case of drug patents. It is in the public interest to protect the pharmaceutical industry's investment into the discovery of new drugs.").

131. In addition, it is in the public interest to minimize disruption in customers' selection and usage of products with the issuance of a preliminary injunction which precludes long-term utilization of and reliance on an allegedly infringing product. *Critikon, Inc.*, 28 U.S.P.Q. 2d at 1371, (granting a preliminary injunction and finding it in the public interest to minimize disruption in hospitals' selection of safety catheters

even though hospitals had already begun to use the infringing catheter because patentee would most likely succeed at trial on the issue of infringement). If BTG were permitted to enter the market for a period of two years or more pending final adjudication of the claims in this action, and were then enjoined, children and their parents would suffer significant psychological trauma as their physicians undertake the difficult task of explaining why the product they have been using has been taken off the market. In such circumstances, it is in the public interest that the *status quo* be maintained.

August 10, 1995
New York, New York

/s/ CONSTANCE BAKER MOTLEY
Constance Baker Motley
U.S.D.J.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

No. 95-1471

Filed May 20, 1996

BIO-TECHNOLOGY GENERAL CORP.
and BIO-TECHNOLOGY GENERAL (ISRAEL), LTD.,

Plaintiffs-Appellants,

—v.—

GENENTECH, INC.,

Defendant-Appellee.

ORDER

A combined petition for rehearing and suggestion for rehearing in banc having been filed by the APPELLANTS, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the suggestion for rehearing in banc having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the suggestion for rehearing in banc be, and the same hereby is, DECLINED.

The mandate of the court will issue on May 28, 1996.

FOR THE COURT,
FRANCIS X. GINDHART, CLERK

Dated: May 20, 1996

By BRIAN P. LEDUC
Brian P. LeDuc
Associate Chief Deputy Clerk

cc: NORMAN H. ZIVIN
NICHOLAS L. COCH

BIO-TECH GEN V GENENTECH INC, 95-1471
(DCT - 95-0110)

Note: Pursuant to Fed. Cir. R. 47.6, this order is not citable as precedent. It is a public record.

[1] PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

Investigation No. 337-TA-358

Received February 13, 1995

In the Matter of

Certain Recombinantly Produced
Human Growth Hormones

Initial Determination
Paul J. Luckern, Administrative Law Judge

Pursuant to the Notice of Investigation published on September 29, 1993, (58 Fed. Reg. 50954-55), this is the administrative law judge's final initial determination under Commission interim rule 210.53. The administrative law judge hereby determines that the investigation should be terminated and the complaint dismissed with prejudice pursuant to Commission interim rule 210.36(b) as a sanction for complainant's conduct in violation of Commission interim rule 210.30(d)(2) and ground rules 4(ix) and 5, resulting in an incomplete record and violation of the due preocess rights of the respondents. Accordingly, the administrative law judge finds no violation of subsection (a)(1)(B)(i) of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), in the importation into the United States, the sale for importation, or the sale within the United States after importation, of certain recombinantly produced human growth hormones.

In the alternative, should the Commission determine that the conduct of complainant is not sanctionable, and that a final determination can be made on the incomplete record as it was closed on April 24, 1994, the administrative [2] law judge has included in this initial determination an opinion based on that record which finds that there would be, under those circumstances, a violation of said subsection (a)(1)(B)(i) by each of the respondents.

* * *

[7]

VI. BTG'S MOTION NO. 358-133 AND NOVO'S MOTION NO. 358-131 FOR SANCTIONS AND BTG'S MOTION NO. 358-130 AND NOVO'S MOTION NO. 358-132 TO REOPEN[9]

BTG, in its Motion No. 358-133 for sanctions filed on August 29, 1994, argued at 2, 3 that on the record the imposition of sanctions on Genentech is warranted given the adverse effects of Genentech's actions upon BTG's ability to

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[9] BTG moved to reopen the record to put into evidence RBX 414, 415, 416, 417, 418, 419, 420, 421, 422, 423, 424, 425, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 445, 446, 447 and 448. By letter dated September 9, 1994, BTG withdrew its offer of RBX 422. RBX 442, 443 and 444, listed in BTG's motion, were produced during discovery in this investigation, prior to the commencement of the hearing on permanent relief, under ITC production numbers GZ 125/001703-001705, GZ 55/1248-1249 and GZ 55/1245-1246, respectively.

Novo has moved to reopen the record to put into evidence RNX 157, 158, 159, 161, 162, 163, 165, 166, 167, 168, 169 and 170. RNX 160 and 164, listed in Novo's motion, were produced during discovery in this investigation, prior to the hearing on permanent relief, under ITC production numbers GZ 100 2007\2017 and GZ 83 1639-1657, respectively. In its opposition at 10 Genentech argued that Novo's request to admit GLP 02789-02790 should be denied because said document had been produced to Novo during the discovery period under ITC production No. GZ 68 2280-2281. It does not appear that Novo has in fact offered any document bearing the GLP numbers 02789-02790.

use various materials at the PEO hearing and in BTG's post-hearing submissions; and hence the administrative law judge should find the following sanctions:

(1) Rule by initial determination that the determinations as to the validity, enforceability, and infringement by BTG with respect to the '832, '980, and '619 patents[10] in the investigation be rendered against Genentech pursuant to interim rule 210.36(b)(5);

(2) Rule that for the purposes of this investigation, all findings necessary to support denial of relief are taken as established adversely to Genentech pursuant to interim rule 210.36(b)(2); and

[8]

(3) Order Genentech to pay BTG's reasonable expenses, including attorney's fees, in connection with BTG's efforts to obtain the improperly withheld documents pursuant to Rule 210.33(c) of the Final Rules of Practice and Procedure.

Novo, in its Motion No. 358-131 for sanctions, filed on August 29, 1994, argued that concealment, lack of candor, frivolous legal argument and continuing evasion have characterized Genentech's conduct concerning the "GLP" documents; that it is indisputable that weeks before the PEO hearing commenced Genentech knew, or upon any reflection would have recognized, that it no longer had any cognizable claim of privilege in the "GLP" documents as a result of a district court's March 22, 1994 decision in an Indiana multidistrict litigation involving Genentech, Eli Lilly & Company (Lilly) and the University of California (UC); and that at a minimum, Genentech had a duty to bring the decision of the district court to the attention of respondents. It is argued that at no time, whether before, during or after the PEO hearing,

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10 The '832, '980 and '613 patents are the only patents asserted against BTG.

did Genentech bring the March 22 district court ppinion to the attention of respondents, the staff or the Commission. Novo argued that Genentech's pattern of deception and evasiveness was violative of all standards of conduct applicable to this investigation and warrants the most stringent sanction, *viz.* dismissal of the complaint; and that Genentech should not be allowed to continue to use this tribunal to achieve its own ends after so abusing the integrity of this investigation and unfairly prejudicing respondents.

A. Background

On March 16, 1993, complainant Genentech filed a complaint alleging violations of subsection (a)(1)(b) of section 337 of the Tariff Act of 1930, as amended. Letters supplementing the complaint were filed on March 30, March 31, April 5, April 6, April 9, April 12 and April 22. On August 18 complainant [9] filed an amended complaint (FF 630). The Commission on September 21, 1993 instituted an investigation, under section 337, involving certain claims of the '246 patent, '832 patent, '980 patent and '619 patent and naming BTG and Novo as respondents and provisionally accepted a motion for temporary relief filed by Genentech. (FF 631 and Procedural History, *supra).* The notice of investigation was published in the Federal Register on September 29, 1993 (FF 632).

In litigation in the United States District Court for the Southern District of Indiana, complainant Genentech has charged Lilly with infringement of the '980, '832 and '246 patents, in issue in this investigation. In that litigation, pending since 1987, Lilly contends that certain of Genentech's patents, including the '980, '832 and '246 patents, are invalid (FF 634). Consolidated with that litigation is a federal district court litigation between Lilly and Genentech involving the remaining '619 patent in issue in this investigation (FF 635). (The consolidated litigation is hereafter referred to as the "MDL litigation.") UC is also involved in the consolidated litigation.

Included as counsel in this investigation for Genentech is not only counsel from the law firm of Fish and Richardson but also John F. Kidd, Esq. of the law firm of Rogers & Wells. Mr. Kidd is Genentech's lead counsel in the MDL litigation. He also participated in opening argument in April 1994 at the hearing on permanent relief in this investigation. In addition, Stephen Raines, Genentech's Vice President, Intellectual Property, is listed as "Of Counsel" for Genentech in this investigation. Also, Raines signed an "Agreement to Abide By the Terms of The Protective Order (Order No. 2)" in this investigation, which was served on February 17, 1994. Raines further testified at the hearing on permanent relief on April 22, and was present for at least a portion of that hearing (FF 636).

[10] Beginning in October 1993, BTG propounded discovery requests on Genentech in this investigation seeking information regarding the '832 patent, '980 patent and '619 patent that were asserted against it by Genentech (FF 637). Novo, beginning in November 1993, propounded discovery requests on Genentech in this investigation seeking information regarding all of the patents in issue, *viz.* the '246 patent as well as the '832 patent, the '980 patent and the '619 patent, because all four patents were asserted against it by Genentech (FF 638). Discovery was ongoing in the MDL litigation concurrently with the discovery in this investigation (FF 646).

In the MDL litigation, early in November 1993 Genentech "inadvertently" produced approximately sixteen (16) boxes of documents to UC and Lilly bearing "GLP" bates numbers. A "substantial" portion of those documents were alleged to be privileged. Within twenty-four (24) hours after Genentech learned that it had "inadvertently" produced the GLP documents, Genentech filed a motion in the MDL litigation for return of the documents with the GLP bates numbers. The parties in the MDL litigation thereafter conducted discovery (including depositions) concerning the facts and circumstances of Genentech's "inadvertent" production of the materials, which discovery was completed in early January, 1994.

The parties then extensively briefed the issue and by early February 1994, the matter was submitted to Judge Dillin in the MDL litigation for decision (FF 646).

During December 1993, Genentech conducted a review of the "inadvertently" produced documents to UC and Lilly, withdrew its claim of privilege with respect to three boxes (approximately 9,000 pages) of documents, and in late December 1993 Genentech produced to Lilly and UC copies of the documents as to which Genentech was no longer claiming privilege (FF 658).

A hearing on complainant's motion for temporary relief commenced on [11] December 13, 1993, and concluded on December 18. *See* Procedural History, *supra*.

Order No. 25, which issued on October 20, 1993, set the commencement of the evidentiary hearing on the permanent relief phase of this investigation for March 21. Order No. 82, which issued on March 2, 1994, delayed the commencement of the evidentiary hearing until April 11. Said hearing concluded on April 24, 1994, at which time the record was closed. Initial post-hearing submissions were filed on May 23, and reply post-hearing submissions on June 3. Closing arguments were had on June 9 and 10 (FF 650).

Taking of discovery after a scheduled discovery completion date has been permitted in this investigation. Thus, while the discovery completion date in the TEO phase of this investigation was December 6, 1993, at least the deposition of Gottesman and Blech, which were admitted into evidence at the TEO and PEO hearings, were taken after the TEO discovery completion date had passed. Moreover, while the discovery completion date for the PEO phase of this investigation was March 18, 1994, at least the following depositions, which were also admitted into evidence at the PEO hearing, were taken after the PEO discovery completion date had passed: Kleid, Chamberlin, Lin, Goodman, Goedell, and Heyneker. In addition, during the hearing on permanent relief, the administrative law judge ruled that certain proffered evidence of complainant would be admitted into evidence provided that Novo, after the April 24 closing date for the

hearing, was given the opportunity to examine certain witnesses. Complainant subsequently withdrew its proffer of said evidence (FF 651).

Because identical patents are involved in the MDL litigation and in this investigation, Genentech knew by at least in March 1994, that certain documents generated in the MDL litigation were responsive to discovery requests propounded by the respondents in this investigation, and that such documents were being produced to BTG and Novo under the protective order in this investigation (FF **[12]** 642).

On March 22, 1994, Judge Dillin denied Genentech's motion in the MDL litigation for the return of 12,000 pages of inadvertently produced documents to Lilly and UC (the "GLP" documents). In the opinion denying Genentech's motion (MDL opinion) Judge Dillin did "not find a subject matter waiver . . . [and hence] the waiver [applied]. . . only to the documents actually produced" (FF 644). Genentech did not seek any appeal of Judge Dillin's denial of its motion (FF 645). Judge Dillin's opinion was published at 30 USPQ2d 1881 on June 27, 1994 (FF 644). Genentech never informed Novo, BTG or the staff about the issuance of the MDL opinion (FF 645).

BTG's counsel, in a letter dated Friday, July 8, 1994, and faxed to Genentech's counsel, referred to the MDL opinion "just published this week" and represented that from the facts available to BTG, BTG believes that many, if not all, of the approximately 12,000 documents involved in the MDL opinion were covered by BTG's discovery requests to Genentech and are relevant to the issues in this investigation; and that BTG's records indicate that no additional documents, such as the ones at issue in the MDL opinion were produced to BTG after issuance of the MDL opinion on March 22, 1994, and that if production were not made, then Genentech is in violation of the administrative law judge's ground rule 4(ix) (FF 653) in effect in this investigation. It was requested, in the July 8 letter, that Genentech confirm that the 12,000 documents referred to in the MDL opinion were in fact produced to BTG, and that if said documents were not produced, but

had been withheld on the ground of privilege, that they be produced to BTG immediately so that BTG can determine whether it will need to make a motion to reopen the record to introduce any documents that it concludes should have been part of the record in this investigation (FF 652).

Genentech's counsel, in a fax letter dated Friday, July 8, 1994, [13] responding to BTG's July 8 letter, stated that Genentech is "presently looking into the matters raised in your letter and will get beck to you early next week" (FF 654).

In a fax letter to complainant's counsel dated Tuesday, July 12, 1994, BTG stated that it had heard nothing from Genentech since "your fax letter of July 8, 1994, stating that you are looking into the matter of Genentech's withheld documents in view of the MDL order [MDL opinion]"; that it is very important that BTG receive Genentech's documents in issue in the MDL opinion since the period during which the administrative law judge may decide the case is rapidly drawing to a close;[11] and that accordingly, unless BTG received copies of the withheld documents by the close of business on July 13, BTG would move before the administrative law judge for appropriate relief (FF 655).

Genentech's counsel, in a July 13 fax letter to BTG's counsel in response to BTG's July 12 letter, represented that "no one is more anxious than Genentech to resolve the issue involving the MDL documents and avoid any potential delay in these proceedings," and that "Genentech and its counsel have been diligently pursuing the matter and we intend to have a formal response to both you and counsel for Novo before the week's end." (FF 656).

In a July 14 letter of Genentech's counsel to counsel for BTG and Novo, responding to the letter of July 8 of BTG's counsel, it was represented that "there is no basis for re-opening the ITC record to include any of these documents" from the MDL litigation that were involved in Judge Dillin's March 22 opinion because the opinion "did not obligate Genentech

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[11] At that time, pursuant to Order No. 82, the final initial determination on permanent relief was due on July 29, 1994.

to produce the privileged materials in this investigation" (FF 657). It was also represented **[14]** that during "the last three days" Genentech had conducted an "exhaustive review" of the approximately 9000 pages of documents it produced to Lilly and UC *in late December 1993*, and no longer claimed were privileged, and determined that approximately 70 percent of those documents were unrelated in any way to growth hormone and/or to the issues relating to the patents in issue in this investigation; that with respect to the remaining approximately 2,900 pages of growth hormone-related documents, all but 60 pages of them were duplicate of documents previously produced to Lilly and UC in the MDL litigation and also produced in this investigation; and that as to the remaining 60 pages of non-privileged growth-hormone-related materials, it was believed they were produced in this investigation, although that had not been established for certain, and in order to avoid any further delay in fully resolving the issues raised by BTG's counsel's July 8 letter, "we voluntarily produce copies of these 60 pages herewith" (FF 658). At a July 26 conference Genentech's counsel Eccleston represented that the sixty documents enclosed with Genentech's July 14 letter to BTG and Novo were responsive to discovery requests of respondents in this investigation and that "we're pretty sure they have been produced [during discovery in this investigation]". Genentech's counsel Kidd represented that:

> some of these [60] documents have been continuously showing up, and I know they've been produced because I've been sitting in a lot of depositions. . . But I think they have been [produced], Mr. Ross thinks they have been and the Fish & Richardson firm thinks that they have been.

(FF 659). Kidd, however, thereafter represented that "[a]nd it turned out that these last 60 pages were the ones that we just couldn't come up with" (FF 659). In a July 28 letter to the administrative law judge, Genentech's counsel represented that it still had not been able to determine that all of the remaining 60 pages were produced during discovery, although

it was confirmed that at least some of the 60 pages were produced and that the balance of the **[15]** remaining pages contains information that is merely cumulative of materials provided to BTG and Novo during discovery (FF 672).

On July 14, 1994, BTG filed Motion No. 358-119 for an order compelling "immediate" production of the GLP documents which (1) in all likelihood were called for by BTG's discovery requests, (2) were found to be not privileged in the MDL opinion and (3) apparently were not produced by complainant in this investigation (FF 660). On July 15, Genentech's counsel in a telephone conference represented that with respect to the documents involved in BTG's Motion No. 358-119 to compel "they are responsive to at least some of BTG's document requests, but we also believe that there's a good likelihood that they have already been produced to BTG" (FF 661).

Genentech's counsel, at the July 15 conference, argued that the waiver in the MDL opinion is:

> for a limited, a very limited purpose of the multidistrict litigation and as to the four corners of the document.
>
> It doesn't apply beyond the multidistrict litigation; it doesn't apply to the ITC; it doesn't apply to other parties, other than UC and Lilly. [FF 661]

BTG argued that what Genentech's counsel said made absolutely no sense; that the documents were found not to be privileged by the district court because there had been a production, and therefore the privilege had been waived; that only as to "other documents dealing with the same subject matter" was there no waiver"; that there is nothing in the MDL opinion that says that the waiver as to the documents involved in the MDL opinion meant that said documents could only be seen by UC and Lilly attorneys; and that counsel for Genentech is on record, both in pleadings, as well as in phone conferences with the administrative law judge, as stating again and again that Genentech has no problem providing documents that were the subject to the MDL protective order **[16]** to counsel in this investigation under the pro-

tective order, provided Lilly and UC had not asserted some kind of confidentiality (FF 661).

On July 15, 1994, Genentech also filed an opposition to BTG's Motion No. 358-119 to compel. It again argued that the MDL opinion did not hold that complainant had waived its privilege for all purposes, but rather that it held that there had been only a limited waiver of privilege as to UC and Lilly in the MDL litigation (FF 662). Genentech, in an August 22 response to Order No. 136, which issued on August 16, repeated its argument that the GLP documents were privileged and BTG and Novo were not entitled to see them because of the very limited nature of the MDL waiver found by the MDL Court and because of the protective order in place in the MDL litigation (FF 680).

Order No. 129, which issued on July 15, ordered that the GLP documents in issue in BTG's Motion No. 358-119 be made available for inspection no later than Tuesday, July 19. Genentech filed no motion for reconsideration of Order No. 129, nor did it request interlocutory review of Order No. 129 (FF 663).

On July 21, pursuant to Order No. 129, each of BTG and Novo filed motions to reopen the record for admission of additional evidence involving the GLP documents produced pursuant to Order No. 129 and for sanctions and to delay the issuance of the initial determination, then due on July 29, until November 29, 1994, at the latest (FF 665). The underlying reason for the motions was to permit sufficient time for the respondents and the administrative law judge to examine and analyze "newly produced evidence" that had been "improperly" withheld by Genentech (FF 665).

On July 25, Genentech opposed the motions filed by the respondents on July 21. Genentech argued that the documents which the respondents saw "for the first time last week," were attorney work product and/or privileged attorney-client communications; that for the most part, those documents contain merely [17] the analyses, musings, ruminations and thought processes of Genentech's counsel and would-be counsel; that those documents do not constitute "new" evidence, nor do they refer to evidence previously unknown to BTG and Novo

and any underlying factual information even present in said documents was available to BTG and Novo during discovery; and that it is the eleventh hour in these proceedings and the final initial determination is due in "only a few days." Genentech, however, also argued that if the administrative law judge does grant respondents' motions to reopen the record, the administrative law judge should adhere to the district court's ruling in the MDL litigation that there has been no subject matter waiver and that any waiver extended only to the four corners of the documents that have been produced which would not preclude the administrative law judge from allowing further depositions, affidavits, or trial testimony concerning each of the documents, which Genentech expects will be necessary in the event that the record is reopened (FF 665).

In the conference before the administrative law judge on July 26, Genentech's counsel represented that because of the protective order in the MDL litigation, any privilege attached to the documents ordered to be produced pursuant to Order No. 129 starting on July 19, was "just waived with the purpose of the MDL litigation" and that "[w]e at [sic] the lead counsel didn't even know about [sic] that this order [MDL opinion] had issued. Because Genentech really believed that it was just a waiver in the case. And we were just completely unaware of this" (FF 668). Genentech's counsel also represented that "[t]here's nothing that they [respondents] have requested that they're entitled to that they have not gotten," and that "[e]verything we could do internally has been done . . . [although] [w]e have not checked with Lilly" (FF 669, 670). Novo, by letter to the administrative law judge dated July 27, 1994, stated that the July 26 conference called into question whether complainant had fully complied with [18] discovery requests in this investigation; that none of at least fourteen relevant documents attached to Novo's motion to reopen filed July 21 were produced to Novo "before last week"; and that only one of the 14 documents was listed in the *Duplan* sheets[12] provided to Novo pursuant to ground rule

[12] The term "*Duplan* sheets" refers to privileged documents list such as explained in *Duplan v. Deering Milliken, Inc.*, 184 USPQ 775 (D.S.C. 1975) (*Duplan*).

5(i)(b) (FF 671). Genentech's counsel, in a July 28 letter to the administrative law judge, represented that with respect to the non-privileged GLP documents missing from Genentech's earlier productions to BTG and Novo, "we have been able to locate those documents at Genentech. They are being sent from Genentech to Rogers & Wells [complainant's counsel], and will be produced to respondents in New York by close of business today" (FF 672). In a letter to counsel for BTG and counsel for Novo dated July 28, Genentech's counsel represented that "[b]y the end of business today, we will send you (1) the documents which you contend were 'missing' from last week's production; (2) more legible copies of certain documents produced last week; and (3) certain additional pages of purportedly 'incomplete' documents produced last week" (FF 673). Those items (1), (2) and (3) were sent by letter dated July 29 (FF 679).

On July 28, 1994, the administrative law judge, in view of the production of documents by Genentech to Novo and BTG commencing on July 19, issued Order No. 132 (an initial determination) granting respondents' motions filed on July 21 to the extent that he delayed the issuance of any final initial determination on permanent relief from July 29, 1994, until November 29, 1994, at the latest. The November 29, 1994, date is the latest date under which the administrative law judge must act under the statutory definition of "more complicated" (FF 674).

[19] Order No. 133, which also issued on July 28, 1994, denied without prejudice respondents' motions filed on July 21, to the extent that they requested reopening the record and sanctions, on procedural grounds in view of the fact that neither BTG nor Novo specifically identified any documents which it wanted admitted into evidence. Order No. 133 concluded that if any of the respondents intend to renew said motions to reopen and for sanctions it should be done no later than August 19, and gave complainant until August 29 to respond to any such renewed motions filed by respondents (FF 676, 677).

Order No. 134, which issued on July 28, 1994, directed complainant to respond by August 4 to certain issues raised by the respondents at the July 26 conference concerning Genentech's production of documents which commenced on July 19 (FF 678). Order No. 134 concluded that if there are still outstanding issues with respect to the production ordered by the administrative law judge pursuant to Order No. 129, a party should notify the administrative law judge in writing no later than August 5, subsequent to discussions with complainant and a telephone conference thereafter will be scheduled (FF 678). Letters dated August 5 from each of BTG and Novo were received by the administrative law judge raising questions concerning Genentech's production which commenced on July 19 (FF 686, 687).

On August 8, the administrative law judge conducted a telephone conference with the parties pursuant to Order No. 134 and the August 5 letters received from counsel for Novo and BTG. As stated at the telephone conference on August 8 and in Order No. 135, which issued on August 8, 1994, the administrative law judge reopened the record for discovery by respondents and the staff "in connection with documents produced by complainant pursuant to Order No. 129" (Order No. 135 at 1) (FF 689(a)).

On August 12, the administrative law judge received motions to compel from **[20]** BTG and Novo, pursuant to Order No. 135, as a result of discovery served by respondents also pursuant to Order No. 135. In issue in the motions to compel, *inter alia*, was whether Genentech identified on its *Duplan* sheets, which were received by respondents prior to the hearing on permanent relief, *all* of its documents that were responsive to discovery requests of respondents but that were not produced to respondents prior to the hearing. Under ground rule 5 in effect in this investigation respondents were entitled to *complete Duplan* lists before hearing. It is a fact that Genentech did not identify on its *Duplan* sheets, which were received by respondents prior to said hearing, all of its documents that were responsive to respondents' discovery requests (*see* FF 690).

Order No. 136, which issued on August 16, responding to respondents' motions to compel, found certain discovery responses incomplete (FF 693). Accordingly, Order No. 136 ordered Genentech to complete certain discovery requests of BTG and Novo by August 22. In view of the incomplete responses of Genentech, Order No. 136 extended the August 19 date for the filing by respondents of any renewed motions to reopen and for sanctions to August 29. A date of September 2 was set for complainant to respond to any such renewed motions (FF 693). Genentech replied to the staff's response to the renewed motions on September 12.

B. Respondents' Motions for Sanctions

1. Genentech's Arguments

In the "Consolidated Memorandum of Genentech, Inc. In Opposition to Respondents' Motion For Sanctions and Motions to Reopen the Proceedings," which was filed on September 2, 1994 (opposition), Genentech argued with respect to "the recourse of sanction to remedy the GLP situation" that

> the only appropriate course is to reopen the record to give respondents (and the Staff) a reasonable *opportunity* (a) to show why any *truly new evidence* should be admitted into the record, and **[21]** upon that showing, and (b) to admit the evidence in a hearing in which the parties have the opportunity to argue how that new evidence is relevant to their "claim," in the context of a hearing where Genentech produces whatever witnesses are ordered by the Administrative Law Judge . . . and where the new evidence may properly be considered by all parties.

Opposition at 2-3 (emphasis in original).

In "Genentech's Reply To The Staff's Response To Respondents' Motion's To Reopen The Record And For Sanctions," which reply was filed on September 12, 1994, Genentech argued at 2-3 that the staff has attempted to put its own

interpretation on certain of the GLP documents; that the staff would have the administrative law judge ignore certain documents on the ground of relevance, and has distilled bits and pieces from other documents, and given the staff's own view on why the documents may be relevant to some issues in this investigation; and that the administrative law judge now has before him a "potpourri" of possible interpretations of the GLP documents from which he can pick and choose, none of which has been put into context by any live witnesses having actual knowledge of the documents. Hence, Genentech argued that any interpretation of the GLP documents would be based on pure speculation and inference. Genentech further included, as an Appendix A to its opposition, "Genentech's Proposed Rebuttal Findings to Novo's Proposed Facts/Adverse Inferences From the GLP Documents."

Genentech has also argued (opposition at 17-19) that the sanctions sought by respondents would *not* be available under Rule 37(b) of the Federal Rules of Civil Procedure, because Genentech has not defied a specific discovery order, and hence no sanction under Commission interim rule 210.36(b) is available.

Genentech argued further (opposition at 20) that any sanction of dismissal is draconian, punitive and implicates due process concerns; that there are limitations on a court's discretion to impose sanctions under Rule 37(b) of the [22] Federal Rules of Civil Procedure which sanctions must be "just" and must be specifically related to the particular "claim" which was at issue in any discovery order. Genentech also argued (opposition at 24, 31) that under the sanctions specifically authorized by Commission interim rule 210.36(b)(5), the rule has the following language not found in Rule 37(b):

> It shall be the duty of the parties to seek, and that of the administrative law judge to grant, such of the foregoing means of relief or other appropriate relief as may be sufficient to compensate for the lack of withheld testimony, documents, or other evidence.

Hence it argued that the language of said rule does not permit sanctions to be imposed except to make up for unavailable evidence. Genentech also argued (opposition at 24-25) that any relief must be the minimum necessary to accomplish the purpose of the interim rule of compensating for a lack of evidence, and a hearing in which all of the parties have the opportunity to develop the record with respect to the GLP documents produced by Genentech would be such a measure of relief; and that evidentiary sanctions are highly disfavored because they frustrate the statutory obligation to make statutory determinations on the basis of a "fully developed factual record."

2. Ruling

a. Monetary Sanctions

At the outset, BTG's request in its Motion No. 358-133 that Genentech be ordered as a sanction to pay BTG's reasonable expenses, including attorneys fees, in connection with BTG's efforts to obtain the GLP documents is denied. This investigation was instituted on September 21, 1993. The Commission's final rule 210.33(c), relied upon by BTG, expressly applies only to those section 337 investigations "that are instituted after August 31, 1994." 59 Fed. Reg. 39020 (Aug. 1, 1994). Costs and attorney's fees are not available under the Commission's interim rules which apply to this investigation. Thus, the [23] Commission's 1988 comments on Commission interim rule 210.36 state that "[t]he Commission will determine at a later date whether to publish proposed rules governing issuance of orders directing the payment of costs and attorneys fees as a sanction for abuse of discovery." Interim Rules Governing Investigations and Enforcement Procedures Pertaining to Unfair Practices in Import Trade, 53 Fed. Reg. 33043, 33052 (Aug. 29, 1988) (1988 Comments). No such rule was proposed by the Commission until it published *proposed* final rule 210.33 in late 1992. 57 Fed. Reg. 52830, 52879 (Nov. 5, 1992). In addition, concerning the Commission's authority to award monetary sanction under its interim rules, the Commission stated in *Certain Concealed*

Cabinet Hinges and Mounting Plates, Inv. No. 337-TA-289 (*Hinges*) that "while express authority to make such awards was granted by Congress in the 1988 amendments to section 337, specifically 19 U.S.C. 1337(h), the Commission declined to implement its authority to award attorneys fees in promulgating the interim rules." *Hinges*, Commission Opinion at 14 (1989).[13]

b. Due Process in Section 337 Investigations

Any section 337 investigation must be conducted pursuant to the Administrative Procedure Act (APA), 5 U.S.C. § 500, *et. seq.*[14] The APA requires, *inter alia*, (1) that the Commission provide parties with the opportunity "for **[24]** submission and consideration of facts," 5 U.S.C. § 554(c)(1); (2) that the Commission may take depositions or have depositions taken "when the ends of justice would be served," 5 U.S.C. § 556(c)(4); and (3) that a party is entitled to present his case, submit a rebuttal case, and conduct cross-examination as necessary for a "full and true disclosure" of the facts, 5 U.S.C. § 556(d). It is "a basic obligation of the ALJ to develop a full and *fair* record." *Smith v. Secretary of Health Education and Welfare*, 587 F.2d 857, 860 (7th Cir. 1978) (emphasis added), citing *Daniels v. Mathews*, 567 F.2d 845 (8th Cir. 1977). Moreover, if an agency has adopted rules for discovery it is bound by those rules and must ensure that its discovery procedures meet the requirements of due process.

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[13] Genentech argued (opposition at 5) that "in addition to the relief or sanctions of the reopened hearing with Genentech required to produce witnesses, Genentech does not oppose reimbursing Novo and BTG their reasonable expenses in reassembling for a hearing on the documents." Genentech did not refer to respondents' costs to obtain the improperly withheld GLP documents. Genentech, however, appears to recognize that some sanction is warranted. As found by the administrative law judge, costs and attorney's fees are not available under the Commission interim rules.

[14] Section 337(c) provides that "[e]ach determination under subsection (d) [concerning permanent relief] . . . of this section shall be made on the record after notice and a opportunity for a hearing in conformity with the provisions of subchapter II of subchapter 5 of Title 5." 19 U.S.C. § 1337(c) (1994).

McClelland v. Andrus, 606 F.2d 1278, 1285-86 (D.C. Cir. 1979) (*McClelland*).[15] In *McClelland*, the D.C. Circuit held that "violence" could be done to "our conception of fair procedure and due process" by denying discovery of a report that it found "might identify individuals that appellant may wish to call as witnesses" and "may lead appellant to additional evidence supportive of his claims." *McClelland*, 606 F.2d at 1286.

Due process "mandates that a judicial proceeding [in a federal district court] give all parties an opportunity to be heard on the *critical and decisive allegations* which go to the *core* of the parties' claim or defense and to present evidence on the contested facts." *Complaint of Bakers' Trust Company*, 752 F.2d **[25]** 874, 890 (3rd Cir. 1984) (*Bakers' Trust*) (emphasis in original). A district court, however, faced with the post-trial production of a large number of documents responsive to earlier propounded discovery requests generally can delay issuance of its decision; order the parties to conduct any additional discovery on the documents as necessary; assess the fees and costs incurred in such additional discovery against the party responsible for the late production; and conduct a supplementary trial on the late-produced documents, with fees and costs incurred in such a proceeding assessed against the responsible party, and with the court's decision to issue sometime thereafter. As already stated, *supra*, in a section 337 investigation under the interim rules, the administrative law judge does not have the authority to award costs and fees to

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[15] The Commission's interim rules were promulgated to allow the parties to take broad discovery in order to develop the relevant issues. The ability of a party to take discovery on the issues presented in an investigation in preparation for the hearing is a significant due process consideration. *Hinges*, Order No. 31 at 6-7 (April 28, 1989) (denying motion to add respondent one month before discovery completion) and Order No. 41 at 3 (May 9, 1989) (heavy burden on party seeking to amend complaint where due process rights to full participation and discovery are prejudiced). *See also Certain Track Lighting System Components, Including Plug Boxes*, Inv. No. 337-TA-286, Order No. 23 at 3 (March 10, 1989) ("Due process requires fairness in preparation for trial as well as fair opportunity for both sides to make a good evidentiary record").

a party victimized by the discovery misconduct of another party. Moreover, the deadline for the completion of a section 337 investigation is fixed by the applicable statute and cannot be extended. Pursuant to Commission interim rule 210.53(a), the final initial determination of the administrative law judge in this investigation must be filed with the Commission no later than November 29, 1994.[16] Complainant Genentech has been aware of the statutory deadline since the notice of the investigation was published in the Federal Register on September 29, 1993.[17] Hence, Genentech's conduct and the respondents' respective motions for sanctions must be viewed not only in the light of the APA, but also in the light of the deadlines imposed by section 337.

[26] The administrative law judge finds, *infra,* that there was gross negligence on the part of Genentech in not identifying certain GLP documents on *Duplan* lists submitted to the respondents before the April 11 commencement of the hearing on permanent relief, *and* in not *commencing* production of the GLP documents until ordered to do so by the administrative law judge on July 19, and that such gross negligence justifies the severest disciplinary measures available under Commission interim rule 210.36(b), *viz.* an order of dismissal. In this investigation it is inarguable that there are material issues of fact in dispute to which the GLP documents relate, and that said GLP documents may have led respondents to the discovery of additional evidence supportive of their claims. Genentech's failure to commence production of the GLP documents subsequent to the issuance of the MDL opinion, until ordered to do so by the administrative law judge, has violated irreparably the due process rights of respondents.

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[16] The administrative law judge knows of no statutory authority whereby said date may be extended.

[17] At least one commentator has stated that the attractiveness of section 337 investigations to complainants is "chiefly attributable to the relatively quick decision attainable under the statutory time limits." Donald K. Duvall, *Unfair Competition and the ITC* § 1.4 at 9 (1994 ed.). However, the rapid adjudication of section 337 investigations is not to be accomplished at the expense of a respondent's right to a fair opportunity to respond to a complainant's allegations and to present its case.

c. Authority to Impose Sanctions Pursuant to Commission Interim Rule 210.36(b)

The Tariff Act of 1930, as amended, states as follows:

> **(h) Sanctions for abuse of discovery and abuse of process**
>
> The Commission may by rule prescribe sanctions for abuse of discovery and abuse of process *to the extent* authorized by Rule 11 and Rule 37 of the Federal Rules of Civil Procedure.

19 U.S.C. § 1337(h)(1994) (emphasis added).[18] In August 1988, the Commission promulgated its interim rules, including Commission interim rule 210.36(b),[19] **[27]** which are in

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[18] Subsection (h) was added to section 337 by section 1342(a)(5) of the Omnibus Trade Act of 1988, Pub.L. 100-418.

[19] Commission interim rule 210.36(b) provides as follows:

> **(b) Failure to comply with order compelling discovery.** If a party or an officer or agent of a party fails to comply with an order *including, but not limited to,* an order for the taking of a deposition or the production of documents, an order to answer interrogatories, an order issued pursuant to a request for admissions, or an order to comply with a subpoena, the administrative law judge, for the purpose of permitting resolution of relevant issues and disposition of the investigation without unnecessary delay despite the failure to comply, may take such action in regard thereto as is just, *including, but not limited to* the following;
>
> (1) Infer that the admission, testimony, documents, or other evidence would have been adverse to the party;
>
> (2) Rule that for the purposes of the investigation the matter or matters concerning the order or subpoena issued be taken as established adversely to the party;
>
> (3) Rule that the party may not introduce into evidence or otherwise rely upon testimony by the party, officer, or agent, or documents, or other material in support of his position in the investigation;
>
> (4) Rule that the party may not be heard to object to introduction and use of secondary evidence to show what the with-

effect in this investigation. In the Commission's 1988 comments to the interim rules, it stated the following with respect to Commission interim rule 210.36:

> **Section 210.36**
>
> . . . section 1342(a)(5)(B) of the Omnibus Trade Act created a new subsection (h) of section 337, which authorizes the Commission to prescribe rules for imposing sanctions for abuse of discovery in **[28]** section 337 investigations to the extent sanctions could be imposed by a Federal District Court under Rule 37 of the FRCP.
>
> The Commission rule governing sanctions for abuse of discovery is § 210.36. It has not been revised, for the following reasons. *The existing provisions of § 210.36 provide sanctions that are comparable to those available under FRCP 37, except that there is no provision for a sanction order directing payment of a party's costs and attorneys' fees.*

1988 Comments, 53 Fed. Reg. at 33052 (emphasis added).[20] Thus it is clear that the Commission intends for Commission

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held admission, testimony, documents, or other evidence would have shown;

(5) Rule that a motion or other submission by the party concerning the order or subpoena issued be stricken or *rule by initial determination that a determination in the investigation be rendered against the party*, or both. Any such action may be taken by written or oral order issued in the course of the investigation or by inclusion in the initial determination of the administrative law judge. It shall be the duty of the parties to seek, and that of the administrative law judge to grant, such of the foregoing means of relief or other appropriate relief as may be sufficient to compensate for the lack of withheld testimony, documents, or other evidence. If in the administrative law judge's opinion such relief would not be sufficient, the administrative law judge shall certify to the Commission a request that court enforcement of the subpoena or other discovery order be sought.

(Emphasis added).

[20] In its opposition at 17, Genentech agreed that Congress in 1988 amended Section 337, such that the Commission may prescribe sanctions to the extent that the federal courts may impose sanctions under Rule 37.

interim rule 210.36(b) and Rule 37(b) of the Federal Rules of Civil Procedure to be coextensive.[21]

The administrative law judge finds that Genentech has violated Commission interim rule 210.30(d)(2) and two of his ground rules which guarantee respondents' due process rights, *viz.* ground rules 4(ix) and 5. Commission interim rule 210.30(d)(2) imposes a duty to supplement responses to discovery requests as follows:

> (2) A party is under a duty to seasonably amend a prior response if he obtains information upon the basis of which—
>
> * * *
>
> (ii) He knows that the response, though correct when made, is no longer true, and the circumstances are such that a failure to amend the response is in substance a knowing concealment.[22]

Ground rules 4(ix) and 5, of which complainant had notice on September 22, **[29]** 1993,[23] compel certain conduct by the parties during the discovery phase of an investigation. Thus ground rule 4(ix) provides as follows:

> (ix) A duty to timely supplement all discovery responses upon obtaining information *rendering a response substantially incomplete or incorrect* is hereby imposed by

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21 While Commission interim rule 210.36(b) refers to "Failure to comply with order compelling discovery," *supra*, the Commission's comments indicate that the Commission intends sanctions to issue under Commission interim rule 210.36(b) just as sanctions would issue under Rule 37(b), which rule covers the failure to comply with any "order to provide or permit discovery" and is not limited to orders compelling discovery pursuant to a motion to compel.

22 Commission interim rule 210.30(d)(2) was based on the language of Rule 26(e)(2) of the Federal Rules of Civil Procedure before that rule was amended in 1993.

23 Ground rule 4(ix) and 5 were put into effect in this investigation with the issuance of Order No. 1 on September 22, 1993, and have remained unaltered throughout the course of the investigation.

> the administrative law judge pursuant to Commission interim rule 210.30(d)(3). [Emphasis added.]

Ground rule 4(ix), which supplements Commission interim rule 210.30(d)(2), ensures that the party upon whom a discovery request is served cannot conceal responsive information which renders a prior response substantially incomplete or incorrect. Ground rule 5 provides for a procedure for the identification of documents with respect to which "there is no objection to production . . . other than that the document is subject to a claim of privilege," whereby certain information relevant to the document and the claimed privilege is set forth in a privileged document list as in *Duplan*, *supra*.[24] (FF 691).

Genentech has argued that it was neither obligated nor able to produce the GLP documents because (1) under the MDL opinion the waiver of privilege applied only to the MDL litigation since the district court judge did not find that there was a "subject matter waiver" of the privilege (FF 657, 661, 662, 666, 668, 681), and (2) Genentech's lead counsel in this investigation was unaware of the issuance of the MDL opinion (FF 668).

Genentech's reliance on the lack of any subject matter waiver is unsupported by federal case law on point, as well as confusing and misleading. **[30]** The issue, which Genentech has failed to address, is whether the privilege that was claimed in the GLP documents actually disclosed to Lilly and UC, which privilege was deemed by the district court to have been waived, is also waived as to the respondents in this investigation, and not whether there was any "subject matter waiver."[25] As stated in Order No. 129, which issued on

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[24] Ground rule 5 puts the requesting party on notice of documents which are responsive to discovery requests and which would be produced to the requesting party, but for a claim of privilege, thus enabling the requesting party to challenge, if desired, the propriety of the privilege claimed prior to any hearing and/or before the record is closed. Genentech's conduct as to certain of the GLP documents, before issuance of the MDL opinion, denied respondents that opportunity.

[25] The doctrine of subject matter waiver applies where a claimed attorney client privilege in a document or other communication is deemed to have been waived and the court further finds that, as a result,

July 19, Genentech has cited nothing in the MDL opinion or elsewhere indicating that the waiver of privilege found by Judge Dillin as to the GLP documents was limited to UC and Lilly.[26] Moreover, it is clear that confidentiality is essential to the maintenance of the attorney-client privilege, Ethan Horwitz and Lester Horwitz, Patent Litigation: Procedure and Tactics § 5.01[4][iii] (1994), citing *Duplan*, *supra*, and when such confidentiality is breached, the privilege should be deemed to have been waived as to any future litigation. *See e.g.*, *Chubb v. National Bank*, 224 USPQ 1002 (D.D.C. 1984); *In re Natta*, 163 USPQ 680 (D. Del. 1969).

The administrative law judge also rejects Genentech's second argument that its lead counsel in this investigation didn't even know that the MDL opinion had issued. Genentech's lead counsel in the MDL litigation, who is listed as counsel for Genentech in this investigation, *and* who participated in opening **[31]** argument in April 1994 at the hearing in this investigation on permanent relief, acknowledged receipt of the MDL opinion (FF 636). Moreover, Genentech's Vice President for Intellectual Property is "Of Counsel" for Genentech in this investigation, and was active at the hearing on permanent relief in this investigation (FF 636). Hence, at least certain counsel for Genentech active in this investigation, as well as Genentech's own in house counsel, knew about the issuance of the MDL opinion and either knew or should have known about the significance of that opinion for this inves-

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any claimed attorney-client privilege in all other documents or communications dealing with the same subject matter is also deemed to have been waived. *See e.g.*, *International Telephone and Telegraph Corp. v. United Telephone Company of Florida*, 60 F.R.D. 177, 185-86 (M.D. Fla. 1973). Federal courts have held that the inadvertent disclosure of certain privileged documents does *not* result in the general waiver of privilege in other undisclosed documents on the same subject matter. *See e.g.*, *Champion Int'l Corp. v. International Paper Co.*, 486 F.Supp. 1328 (N.D. Ga. 1980); *Golden Valley Microwave Foods v. Weaver popcorn Co.*, 18 USPQ2d 1867 (N.D. Ind. 1990); *International Digital Sys. v. Digital Equip. Corp.*, 120 F.R.D. 145, 146 n.2 (D. Mass. 1988).

[26] Genentech sought neither reconsideration nor interlocutory review of Order No. 129.

tigation. In addition, Genentech knew at least by March 1994, that documents generated in the MDL litigation were relevant to issues in this proceeding (FF 642, 643). Moreover, Genentech was very much involved with the GLP documents in the MDL litigation while discovery was being pursued by Genentech in this investigation (FF 646).

Had Genentech produced the GLP documents after issuance of the MDL opinion, respondents would have had the opportunity to conduct any additional discovery, including discovery depositions, necessitated by their production, and would have had the opportunity to complete the record and prepare fully for any hearing or continuation of said hearing.[27] Instead, as a result of Genentech's failure to comply with Commission interim rule 210.30(d)(2) and ground rules 4(ix) and 5, respondents were precluded from conducting such discovery and from offering the GLP documents into evidence at the hearing on permanent relief. What effect the GLP documents would have had on this **[32]** investigation, either in themselves or in leading to the discovery of other admissible evidence, is unknown. It is known that GLP documents responsive to respondents' discovery requests were not produced by Genentech during the discovery period. Accordingly, the administrative law judge finds, as a result of Genentech's conduct, that the record as it now stands is incomplete.

While Genentech has acknowledged the duty to supplement discovery imposed by Commission interim rule 210.30(d)(2) and ground rule 4(ix) (FF 666), it has also maintained that it was under no duty to supplement its discovery requests under the instant circumstances because: (1) the duty to supplement discovery responses extends only until the close of discovery,

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[27] In at least two previous investigations of this administrative law judge large numbers of relevant documents were either produced or discovered near the end of the discovery period and, as a result, the hearing dates were delayed. *Certain Integrated Circuit Telecommunication Chips and Products Containing Same, Including Dialing Apparatus*, Inv. No. 337-TA-337, Order No. 86 at 1, 14 n.8, 18 (Oct. 14, 1992); *Certain Aramid Fiber*, Inv. No. 337-TA-194, Order No. 13 at 1011, 13 (Oct. 31, 1984). In addition, even in this investigation, discovery was taken after the discovery cut-off date (FF 651).

which was March 18, whereas the MDL opinion issued on March 22, after the close of discovery; (2) the new information did not render Genentech's discovery responses substantially incomplete or inaccurate; and (3) Genentech did not knowingly conceal any information (FF 666).

Contrary to Genentech's argument, the duty to supplement discovery requests extended *at least* until the close of the record upon completion of the hearing, especially where the withholding party had been aware of the information, as Genentech was aware of the MDL opinion, prior to the record being closed. Nothing in Commission interim rule 210.30(d)(2) or in Rule 26(e) of the Federal Rules of Civil Procedure limits the duty to supplement to the end of any discovery period. The Notes of the Advisory Committee on Rules state, with respect to the 1993 amendment to Rule 26(e), that "[t]he obligation to supplement disclosures and discovery responses applies *whenever* a party learns that its prior disclosure or responses are in some material respect incomplete or incorrect." In addition, as Genentech is aware, the discovery cut-off date **[33]** set by this adminiustrative law judge is not set in stone but may be extended,[28] and discovery has been allowed in this investigation beyond the discovery completion dates (FF 651). Moreover, hearing dates themselves are flexible. Thus, until the final initial determination is filed with the Commission, any party may move to reopen the record, and discovery may be conducted on any issue at the discretion of the administrative law judge. *Havenfield v. H. & R. Block, Inc.*, 509 F.2d 1263 (8th Cir. 1975) (*Havenfield*), cited by Genentech (FF 666), is inapposite. In *Havenfield*, the Eighth Circuit held the district court did not abuse its discretion in disallowing the filing of a supplemental discovery response pursuant to a local rule that prohibited the filing of supplemental discovery responses after the close of discovery, absent good cause. *Havenfield*, 509 F.2d at 1271-72. There is no "local rule" at the Commission explicitly or in practice limiting the duty to supplement. Moreover, in *Havenfield* the defendant sought to supplement its *own* previous dis-

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[28] *See, e.g.*, Order No. 68 (Feb. 10, 1994).

covery responses in order to *improve* its position in the litigation, *i.e.* to set forth the new information for its own benefit, and the Court found that in delaying three and one-half to four months before attempting to supplement the appropriate discovery responses, the defendant "was not acting seasonably." *Havenfield*, 509 F.2d at 1272.

The administrative law judge rejects Genentech's argument that the admittedly new information in this investigation did not render its previous responses incomplete or inaccurate. As stated, *supra*, in placing a document on a *Duplan*-type privilege document list, a responding party avers that the document thus listed is responsive to a discovery request *and* that the only basis on which production of the document is withheld is a claim of privilege. **[34]** Thus, when the United States District Court for the Southern District of Indiana held in the MDL opinion that the GLP documents were no longer privileged, this holding *clearly* rendered Genentech's previous responses involving those documents inaccurate (assuming *arguendo* Genentech had listed all of the GLP documents on its *Duplan* sheets), *i.e.* Genentech's assertion of privilege. Whether the content of the GLP documents represents significant or "truly new" evidence is immaterial to the issue of whether Genentech's previous *discovery responses* were inaccurate. The administrative law judge finds that upon issuance of the MDL opinion the GLP documents to which that opinion applied were no longer privileged, and that Genentech was under a duty to supplement discovery responses in which it asserted a privilege as to those documents.

Genentech's argument, *supra*, that its failure to disclose the MDL opinion and produce the GLP documents did not amount to a "knowing concealment" is also rejected. As the Seventh Circuit has stated:

> The strong term "knowing concealment" is designed, in recognition of the burden that a general duty of supplementation would impose in complex litigation, to protect a party who is reasonable in believing either that the change that has made his answer no longer accurate

is known to his opponent or that it is a matter of no importance.

Fortino v. Quasar Company, 950 F.2d 389, 396 (7th Cir. 1991), citing *Johnson v. H.K. Webster, Inc.*, 775 F.2d 1, 8 (1st Cir. 1985). Applying the standard in *Fortino* to Genentech's conduct, the administrative law judge finds that there was no basis for a reasonable belief on Genentech's part that the respondents in this investigation would have obtained knowledge of the issuance of the MDL opinion in March 1994. There is nothing in the record to show that either BTG or Novo was informed by any party in the MDL litigation, or by anyone else, about the issuance of the MDL opinion, or that they had any knowledge about it, until after its publication on June 27. To the contrary, when respondents **[35]** became aware of the MDL opinion through its publication, respondents promptly attempted to obtain from Genentech the GLP documents (FF 652), but were rebuffed by Genentech about a week later on July 14 (FF 657), at which time the final initial determination on permanent relief was due on July 29.

Genentech also has failed to show that it reasonably believed that the MDL opinion was a matter of no importance. To the contrary, in its opposition filed on September 2, Genentech argued for a hearing on the GLP documents, with no opportunity for discovery depositions on the documen by respondents.[29]

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[29] Genentech proposed (opposition at 36) the following procedural schedule:

> Mon., Sept. 19: Identification by respondents and Staff of their previously-identified GLP documents, sponsoring witnesses, and any other witnesses who are expected to give testimony relative to each document;
>
> Wed., Sept. 21: Identification by Genentech of rebuttal documents and witnesses;
>
> Thurs., Sept. 29: Commencement of "GLP hearing" (length to be determined by Administrative Law Judge—assumed, for scheduling purposes, to end on Tuesday, Oct. 4; and assumed that all "requested" witnesses can be available

BTG and Novo, in their Motion Nos. 358-130 and 358-132 to reopen, have each asserted that at least certain of the GLP documents are significant to certain issues in this investigation. Novo, also in its Motion No. 358-132, at footnote 3, argued:

> [36] While a number of documents are of potential significance or could have been the basis for further discovery or deposition questions, Novo Nordisk has made a great effort to winnow these documents, such that those annexed hereto constitute only those which Novo Nordisk believes are sufficiently significant, on their face, to warrant reopening the record to admit them *in the absence* of any further discovery. Had Genentech timely produced the GLP documents, Novo Nordisk, in all likelihood, would have relied on, or otherwise utilized, more, perhaps many more, of the GLP documents. [Emphasis in original].

Due process requires that the respondents should not be limited to considering the GLP documents "on their face," and requires that respondents should have had at least the opportunity for further discovery, including depositions, on the documents and the opportunity to offer them into evidence at the evidentiary hearing on permanent relief. Had Genentech timely produced the GLP documents, respondents would have had those opportunities and been afforded due process.

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	for the hearing); order of presentation—Respondents, Staff, Genentech;
Fri., Oct. 14:	Post-hearing briefs by respondents and Staff (with proposed findings of fact) in support of (a) why their respective GLP documents should be admitted into the record, and (b) how those documents should impact their claims; and
Tues., Oct. 18:	Reply brief by Genentech (with rebuttal findings of fact) (case then under submission to the Administrative Law Judge).

d. Sanctions Are Warranted Under Commission Interim Rule 210.36(b)

As noted, *supra*, the administrative law judge finds that because Genentech has violated Commission interim rule 210.30(d)(2) and his ground rules 4(ix) and 5, sanctions under Commission interim rule 210.36(b) are warranted. He rejects, as without merit, Genentech's argument that no sanction is available under Commission interim rule 210.36(b) or Rule 37(b) of the Federal Rules of Civil Procedure because it has violated no discovery orders contemplated by the those rules (opposition at 17-18, 23-24; reply at 6). Commission interim rule 210.30(d)(2) is a rule imposing a certain *duty* to supplement discovery responses, and ground rules 4(ix) and 5 are discovery orders of the administrative law judge. Federal Courts have held that Rule 26(e) of the Federal Rules of Civil Procedure, which imposes a duty to supplement discovery responses under certain circumstances, does not require that there be an order compelling discovery in place before a court may impose sanctions for violation of the duty to supplement. *Alldread v Grenada*, 988 F.2d 1425, 1436 (1st Cir. [37] 1993); *Thibeault v. Square D Company*, 960 F.2d 239, 245 (5th Cir. 1992). Moreover, if Genentech's illusory argument that it should be spared sanctions because Genentech did not defy a specific order compelling discovery were accepted, then parties in section 337 investigations would be able, through grossly negligent failure to produce requested documents whose privileged status has been lost and/or grossly negligent failure to identify privileged documents, to proceed with a hearing and post-hearing submissions and then argue that an initial determination on the merits should issue, as Genentech argued on July 25 (FF 665), irrespective of the non-production of responsive documents even though its conduct *precluded* the requesting party from filing a timely motion to compel. In other words, in the absence of compliance by Genentech with Commission interim rule 210.30(d)(2) and ground rules 4(ix) and 5, the respondents did not know, and could not have been expected to know, that there was even a basis for filing a motion to compel. Despite

the fact that the MDL opinion issued on March 22, 1994, which was more than two weeks before the start of the permanent relief hearing on April 11, Genentech made no attempt to inform the other parties in the investigation about the MDL opinion. The respondents were thus unable to bring any motion to compel production of the GLP documents until they first learned of MDL the opinion, not through any notification by Genentech, but through publication of the MDL opinion on June 27. Further, when respondents *did* become aware of effect of the MDL opinion, Genentech, although aware that final initial determination was then due on July 29 and that the maximum statutory deadline for any final initial determination was November 29, refused to commence production of the GLP documents until so ordered by the **[38]** administrative law judge on July 15 (FF 663).[30]

In addition, there is precedent in Commission practice for the application of sanctions under Commission interim rule 210.36(b) in the absence of an order compelling discovery issued under Commission interim rule 210.36(a). In *Certain Composite Diamond Coated Textile Machinery Components*, Inv. No. 337-TA-160, Order No. 43 (March 29, 1984) (*Diamond Coated Machinery*), the complainant had inspected certain documents in February 1984 and requested that a number of them be photocopied by respondents. Respondents initially agreed, but later refused to provide copies of the materials, arguing that the documents contained the confidential information of a third party. In its proposed agenda for a discovery conference in early March 1984, complainant stated that the respondents be ordered to produce the documents at issue, but the administrative law judge "did not consider the motion" based on the assurance of respondents' counsel that the documents would be produced. By the time of the hearing in late March 1984, respondents had still not produced the requested documents (again asserting the third party status of the

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30 Indeed, Genentech even opposed Motion Nos. 358-120 and 122 of respondents BTG and Novo, respectively, to delay issuance of the final initial determination on permanent relief, which was due on July 29 (FF 662). *See* Order No. 132 (July 28, 1994).

documents, as well as asserting a relevance objection) and complainant filed a motion for sanctions, which motion the respondents argued should be summarily denied in the absence of any preceding motion to compel under then Rule 210.36(a). *Diamond Coated Machinery*, Order No. 43 at 2-4.

The administrative law judge in *Diamond Coated Machinery* granted the complainant's motion for sanctions. The administrative law judge stated that the respondents had expressed no objection at the discovery conference to the **[39]** production of the documents and "thereby precluded complainant from seeking timely relief such as motion to compel." *Id.* at 4. The administrative law judge went on to state the following regarding the effect of said conduct on the party seeking discovery:

> Whether intentional or not, respondents have misled complainant right up through the March 13 conference, thus prejudicing complainant in its ability to take further steps to obtain the desired discovery. Had respondents given timely notice of their position, complainant may have been able to obtain discovery of the disputed documents (*see e.g., Societe Internationale Pour Participations Industrielles et Commerciales, S.A. v. Rogers*, 357 U.S. 197 (1958)) or found alternative means to obtain its equivalent. . . . respondents *forestalled and prevented complainant from making a timely motion to compel*, as well as pursuing any alternate discovery procedures as might have been available. *Such dilatory conduct comes at least within the spirit of Rule 210.36 and warrants the issuance of sanctions.*

Id. at 5-6 (emphasis added).

As in *Diamond Coated Machinery*, Genentech's conduct in this investigation has affected the ability of the respondents to make a complete record and to fairly prepare for the hearing. Here Genentech, in violation of ground rule 5, initially failed to list *all* of the GLP documents responsive to respondents' discovery requests on its *Duplan* list (FF 690). Thus, with respect to those documents, respondents were completely unaware that those documents (1) were responsive to some of

their requests and (2) were withheld only on the basis of a claim of privilege. Respondents were thus altogether precluded from even attempting to obtain discovery of those documents. Later, upon issuance of the MDL opinion, Genentech, in violation of Commission interim rule 210.30(d)(2) and ground rule 4(ix), failed to produce said documents to respondents and failed even to update its *Duplan* list to put respondents on notice that the documents **[40]** were no longer privileged.[31] Moreover, while in *Diamond Coated Machinery* the complainant at least knew of the existence of the discoverable documents prior to the hearing and sanctions were still issued in that investigation, the respondents in this investigation did not know about the discoverable documents until some two months *after* the hearing, and only then through publication of the MDL opinion rather than by notification from Genentech.

Genentech's attempts to distinguish *Diamond Coated Machinery* are rejected.[32] The fact that *Diamond Coated*

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[31] Referring to the 60 documents produced to respondents by Genentech on July 14, which documents were responsive to certain of respondents' discovery requests and with respect to which Genentech's previous claims of privilege had been withdrawn without notice to the respondents prior to July 14 (FF 666), Genentech has argued that the portion of said documents not produced to respondents prior to July 14 are merely cumulative of documents and information that had been produced already to respondents, and add nothing to the investigation (FF 666). Although it is unclear what portion of said documents were produced to respondents during the discovery period, it is clear that *all* of said documents should have been produced as soon as Genentech's claims of privilege were withdrawn. Whether such documents are "cumulative" of documents already produced is not for Genentech to determine unilaterally. Even if none of the 60 documents above are any part of the basis for the sanctions requested by respondents, Genentech's failure to produce each of said documents during the discovery period is further confirmation of Genentech's inattentive approach to discovery of the GLP documents prior to July 1994.

[32] In its reply to the staff's response to the motions for sanctions Genentech attempted to factually distinguish *Diamond Coated Machinery*, arguing that its order is inapplicable to this investigation because it was issued before the 1988 amendment to the statute that permits sanctions for discovery abuses only to the extent permitted by Rule 37 (reply

Machinery was decided prior to the addition of section 337(h) to the statute is irrelevant. As stated above, upon amendment of the statute in 1988, the Commission issued new rules (the so- **[41]** called "interim rules") to bring Commission practice into compliance with the amended statute. At that time the Commission stated that the rule published as interim rule 210.36 was *unchanged* from the existing rule 210.36, under which *Diamond Coated Machinery* was decided, and stated that further "[t]he existing provisions of § 210.36 provide sanctions that are comparable to those available under FRCP 37." 1988 Comments, 53 Fed. Reg. at 33052. If Commission interim rule 210.36 permitted discovery sanctions beyond those permitted under Rule 37 of the Federal Rules of Civil Procedure, then the Commission would have had to amend it in order to comply with section 337(h).

In addition, the focus of *Diamond Coated Machinery* is that the administrative law judge there, as admitted by Genentech in its reply at 9, determined that because of the conduct of the producing party it was *too late* for a motion to compel. The salient fact in that case, as in this investigation, is that the party in possession of the documents, by its own conduct, "precluded [the other party] from seeking timely relief such as a motion to compel or other alternative discovery." *Diamond Coated Machinery* at 4, *supra*.

Commission interim rule 210.30(d)(2) and ground rules 4(ix) and 5, with clarity and specificity, compel certain conduct by the parties during the course of discovery, and are not general or ambiguous. Thus, they are distinguishable from the orders involved in, for example, *R.W. Int'l Corp. v. Welch*

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at 7); that in *Diamond Coated Machinery* sanctions were imposed upon respondents' failure to provide certain promised discovery, with the administrative law judge "equating" respondents' promise in response to a "timely motion to compel" with an order compelling discovery (*id.*); and that in this investigation, unlike *Diamond Coated Machinery*, any motions to compel "were entertained and complied with," and "there is no missing discovery" since all GLP documents have been produced to respondents (reply at 7-8). Genentech further argued that in *Diamond Coated Machinery* the situation "was not exposed until the hearing," and the administrative law judge there determined that at that stage it was too late for a motion to compel (reply at 8).

Foods, Inc., 937 F.2d 11, 15 (1st Cir. 1991) (*R.W. Int'l Corp.*), cited by the complainant in its opposition.[33] The order in issue in *R.W. Int'l Corp.* was the district [42] court's "Scheduling Order" in which the court gave certain instructions concerning the scope of discovery, the parties were directed to state certain facts regarding their costs, earnings, profits, etc., and certain discovery deadlines were set. When the plaintiff subsequently failed to respond to discovery requests of defendant, and plaintiff's sole shareholder refused to answer certain questions during his deposition, the district court dismissed the case, finding that plaintiff had willfully violated its "discovery orders." The First Circuit reversed, finding that an order "to answer specific . . . questions" could not be implied from the Scheduling Order. *R.W. Int'l Corp.*, 937 F.2d at 13-14, 16. The First Circuit stated that whether plaintiff's failure to produce documents was sanctionable under Rule 37(b)(2) of the Federal Rules of Civil Procedure depended on whether plaintiff had defied a "sufficiently explicit" order, and held that the district court's Scheduling Order was not such a "sufficiently explicit" order, but rather a "general directive," containing "sweeping generalities," "fraught with ambiguities," and "broad brush." *Id.* at 16-18.

Commission interim rule 210.30(d)(2) and ground rules 4(ix) and 5, unlike the Scheduling Order in *R.W. Int'l Corp.*, do not address any vaguely defined categories of documents or discovery requests, but unambiguously apply, respectively, to any and all discovery requests that are rendered incomplete or incorrect by later acquired information and the identification of *any and all* documents with respect to which any

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[33] In support of the proposition that Genentech has violated no orders contemplated by Commission interim rule 210.36(b) or Rule 37(b), Genentech cited *R.W. Int'l Corp.*, citing *Badalamenti v. Dunham's, Inc.*, 896 F.2d 1359, 1362 (Fed. Cir.), *cert. denied sub nom., Hyde Athletic Industries, Inc. v. Badalamenti*, ___ U.S. ___, 111 S.Ct. 142 (1990) (*Badalamenti*); *Salahuddin v. Harris*, 782 F.2d 1127, 1131 (2d Cir. 1986) (*Salahuddin*); 4A J. Moore & J. Lucas, *Moore's Federal Prac.* ¶37.03[2], at 37-62 to 37-64 (2d ed. 1991); 8 C. Wright & A. Miller, *Federal Prac. & Proc.* § 2289 at 790 (1970)); and *GFI Computer Indus., Inc. v. Fry*, 476 F.2d 1, 3 (5th Cir. 1973) (*GFI*).

party claims a privilege. Thus, the First Circuit's criticism that an order to answer a particular deposition question or [43] produce a particular document cannot be implied from a "general order" such as the district court's Scheduling Order, is found not to apply to Commission interim rule 210.30(d)(2) and ground rules 4(ix) and 5.[34]

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[34] *Badalamenti*, *Salahuddin* and *GFI*, *supra*, are similarly inapposite. Neither *Badalamenti* nor *Salahuddin* apply because neither case directly involves Rule 37(b)(2) of the Federal Rules of Civil Procedure. In *Badalamenti*, it was discovered during proceedings on remand that the plaintiff had failed to produce certain documents that were responsive to a Rule 30(b)(5) document request which had been served on plaintiff by defendants with a notice of deposition during the initial proceedings. Defendants moved for, and were granted, sanctions under Rule 37(*d*) which applies only to a complete failure of a party to attend at his own deposition or serve answers to interrogatories or respond to a request for inspection. No sanctions were sought or awarded pursuant to Rule 37(*b*) which applies *only* to a failure at all of a party to attend at his own deposition or serve answers to interrogatories or respond to request for inspection. On appeal the Federal Circuit reversed, holding that although plaintiff's response to the document request was inadequate and failed to include responsive documents, plaintiff *had* responded and thus could not be sanctioned under Rule 37(d). *Badalamenti*, 896 F.2d at 1363. The Court's only references to Rule 37(b), cited by Genentech, is that "Rule 37(b) provides for sanctions where a party fails to comply with a discovery order" and "[t]he district court in this case acknowledged that sanctions under this subdivision were unavailable because there was no discovery order that was violated." *Badalamenti*, 896 F.2d at 1362. This reference by the Court to Rule 37(b)(2) is the merest dicta. Moreover, unlike the plaintiff in *Badalamenti*, Genentech in this investigation has clearly violated Commission interim rule 210.30(d)(2) and ground rules 4(ix) and 5 of Order No. 1.

In *Salahuddin* the district court had ordered the plaintiff's deposition pursuant to Rule 30(a) of the Federal Rules of Civil Procedure, and upon plaintiff's refusal to answer certain questions during the deposition the district court dismissed the case as a sanction pursuant to Rule 37(*d*). The Second Circuit reversed the dismissal and also discussed the applicability of Rule 37(b) to the case, noting that the defendants originally sought sanctions for Salahuddin's deposition conduct under Rule 37(b)(2). The Second Circuit held that although a court order under Rule 37(a) was in effect at the time of the plaintiff's deposition, said order "did not specify what matters could or could not be inquired into at the deposition or what procedures were to be followed if a dispute arose over the manner of conducting the deposition." *Salahuddin*, 782 F.2d at 1131. The Court

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e. Appropriateness of Dismissal As A Sanction Under Commission Interim Rule 210.36(b)

The sanction of dismissal is appropriate in this investigation where, as a result of Genentech's conduct, the record is incomplete and where Genentech's failure to comply with Commission interim rule 210.30(d)(2) and ground rules 4(ix) and 5 is found to amount to gross negligence. Under the language "including, but not limited to" in Commission interim rule 210.36(b), the administrative law judge has broad discretion as to what sanction he may issue, including the rendering of a determination against a party. Commission interim rule 210.36(b)(1)-(5). In addition, Rule 37(b), on which Commission interim rule 210.36(b) is modeled, expressly provides for the entry an order "dismissing the action or proceeding." *See* Fed. r. Civ. P. 37(b)(2)(C).

In *Societe Internationale Pour Participations Indusrielles et Commerciales, S.A. v. Rogers*, 357 U.S. 197 (1958) (*Societe)* the Supreme Court held that, in view of the due process implications in the denial of a party'ys right to be heard, Rule 37 does not authorized dismissal of a case "when it has been

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further noted that the district court "had the power under Rule 37(a) to direct Salahuddin to answer specified questions but it failed to do so," and declined to imply any such order from the Rule 30(a) order. *Salahuddin*, 782 F.2d at 1131-32. The Court thus held that "[t]here was no violation of a court order upon which to base Rule 37(b) sanctions."

Salahuddin is distinguishable from the instant investigation in two respects. First, in *Salahuddin*, like *Badalamenti*, the issue before the Court of Appeals was the application by the district court of sanctions pursuant to Rule 37(d) of the Federal Rules of Civil Procedure and not Rule 37(b)(2). Second, to the extent that *Salahuddin* does apply to Rule 37(b)(2) sanctions, the order in that case, like that in *R.W. Int'l Corp.*, lacks the specificity of ground rule 5 at issue.

In additions the *GFI* case, cited by Genentech, does not apply to this investigation because it was found in that case that the order of the district court that the party against whom sanctions were entered was accused of violating had been "issued under an erroneous view of the facts," and thus could not serve as the basis for a default judgement. *GFI*, 476 F.2d at 5. Commission interim rule 210.30(d)(2) and ground rules 4(ix) and 5 were not issued in error, unlike the order in *GFI*.

established that failure to comply has been due to inability, and not to willfullness, bad faith, or any fault." *Societe*, 357 U.S. at 212. In that case the Supreme Court accepted the arguments of a Swiss party that it was *unable*, despite extensive efforts at compliance with a court order, to produce the [45] douments at issue due to the threat of criminal prosecution under Swiss law relating to production of such documents. *Id.* at 211-12. Interpreting the meaning of the "fault" standard enunciated in *Societe*, the Second Circuit has held that "fault" covers at least gross negligence. *Cince Forty-Second Street Theater, Inc. v. Allied Artists Picture corp.*, 602 F.2d 1062, 1067 (2d Cir. 1979).

Negligence has been described in the context of tort law as the failure to conform to an expected standard of conduct or duty of care resulting in somme harm to another. W. Page Keeton, Prosser & Keeton on the Law of Torts § 30, at 164 (5th ed. 1984) (Prosser & Keeton). Gross negligence "signifies more than ordinary inadvertence or inattention, but less than perhaps conscious indifference to the consequences," and "differs from ordinary negligence only in degree." Prosser & Keeton § 34, at 212 (footnotes and citations omitted). The degree of care owned depends upon the circumstances present.[35] Thus, in a section 337 investigation, in which the time available for discovery is relativley condensed and the time available for completion of the investigation is short and fixed by statute, and in this investigation in particular where the investigation had already been declared "more compli-

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[35] Prosser & Keeton describe how the standard of care owed by one to anther may alter in accordance with the circumstances involved as follows:

> The amount of care demanded by the standard of reasonable conduct must be in proportion to the apparent risk. As the danger becomes greater, the actor is required to exercise caution commesurate with it. Those who deal with instrumentalities that are know to be dangerous . . . must exercise a greate amount of care because the risk is great. They may be required to take every reasonable precaution suggested by experience or prudence.

Prosser & Keeton § 34, at 208 (footnotes and citations omitted).

cated" prior to issuance of **[46]** the MDL opinion,[36] the parties' duty of care in discovery is found to be very high, and each party is expected to "take every reasonable precaution suggested by experience or prudence" in the conduct of discovery. With specific regard to the conduct of discovery, the Second Circuit in *Cine*, in dismissing the case pursuant to Rule 37(b) based on the party's gross negligence, held that gross negligence was present "where counsel clearly *should have understood* his duty to the court." *Cine*, 602 F.2d at 1068 (emphasis added).

The administrative law judge finds that Genentech clearly should have understood its duty under Commission interim rule 210.30(d)(2) and ground rules 4(ix) and 5. Moreover, given the heightended duty of care Genentech was obligated to observe, the administrative law judge finds that Genentech's conduct after issuance of the MDL opinion is grossly negligent in (1) its failure to identify all of the GLP documents responsive to the respondents' discovery requests, in violation of ground rule 5, and (2) its failure to notify respondents' about the MDL opinion and its failure to produce the GLP documents to the respondents after the MDL opinion had issued, in violation of Commission interim rule 210.30(d)(2) and ground rule 4(ix).

The administrative law judge rejects Genentech's argument that the sanction of dismissal is not available to the administrative law judge junder Commission interim rule 210.36(b). While "dismissal" is not expressly provided for in Commission interim rule 210.36(b), the interim rule does expressly provide for its equivalent, *viz.* that an administrative law judge may rule "that a determination in the investigation be rendered against the party." Commission interim rule 210.36(b)(5). Moreoer, Rule 37(b), which the Commission has stated is "comparable" to Commission interim rule 210.36(b), does expressly **[47]** provide for the issuance of an order "dismissing the action or procedding or any part thereof" as a sanction for abuse for discovery. Fed. R. Civ. P. 37(b)(2)(C).

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[36] *See* Order No. 82 (March 2, 1994).

Dismissal is appropriate not only because of the due process owed to respondents, but also because of its important deterrent value. In *Naational Hockey League v. Metropolitan Hockey Club*, 427 U.S. 639 (1976), the Supreme Court articulated the significance of deterrence in the application of Rule 37 sanctions, not only with respect to the individual parties involved, but also with respect to future parties. The Court held that:

> There is a natural tendency on the part of reviewing courts, properly employing the benefit of hindsight, to be heavily influenced by the severity of outright dismissal as a sanction for failure to comply with a discovery order. It is quite reasonable to conclude that a party who has been subjected to such an order will feel duly chastened, so that even though he succeeds in having the order reversed on appeal he will nonetheless comply promptly with future discovery orders of the district court.
>
> But here, as in other areas of the law, the most severe in the spectrum of sanctions provided by statute or rule must be available to the district court in appropriate cases, not merely to peanlize those whose conduct may be deemed to warrant such a sanction, but to deter those, who might be tempted to such conduct in the absence of such a deterrent. If the decision of the Court of Appeals remained undistrubed in this case, it might well be that *these* respondents would faithfully comply with all future discovery orders entered by the District Court in this case. But other parties to other lawsuits would feel freer than we think Rule 37 contemplates they should feel to flout other discovery orders of other district courts.

National Hockey League, 427 U.S. at 642-43 (emphasis in original). *See also Cine*, 602 F.2d at 1066 (recognizing the general deterrent effect of Rule 37 dismissal). Thus the dismissal of this investigation serves not only to avoid prejudice to the respondents who have been deprived of their ability to

fully and fairly prepare their case, but also to deter such conduct in future **[48]** investigation.[37] Deterrence is of particulr concern in the context of complex section 337 investigations in which the maximum statutory limitation is relatively short and fixed, and there can be a temptation to obfuscate or delay discovery, or even to conceal discoverable facts and/or documents.

With respect to the documents respondents wish to have admitted into evidence, Genentech argued that the only appropriate course is to reopen the record to give respondents and the staff a reasonable opportunity to show why any "truly new evidence" should be admitted into this record, and that to admit any GLP document solely on the basis of attorney interpretation and inference is improper where witnesses could be made available to put the documents in proper perspective and context. While the administrative law jduge agrees with Genentech to the extent that the interpretation of any GLP document should not be based solely on attorney interpretation, he does not understand Genentech's use of the term "truly new evidence." The Commission interim rules makes no distinction between "evidence" and "truly new evidence"[38] admissible in an adminstrative hearing under section 337. Moreover, in terms of the impact of the GLP documents on any discovery, the Commission interim rule 210.30(b)

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[37] As one commentator has stated, *National Hockey League*, "which does not present a particularly uncommon instance of discovery abuse, shows that dismissal and default are not exceptional but rather they are simply options available to judes who must respond to conduct which is culpable yet not so blatnatly intentional or one sided as to constitute constructive abandonment." Note, "The Emerging Deterrence Orientation in the Imposition of Discovery Sanctions," 91 Harv. L. Rev. 1033, 1047, 1047 n. 86 (1978).

[38] To the extent that Genentech's phrase "truly new evidence" relates to the reference in Commission interim rule 210.42(b) to the inadmissibility of "unduly repetitious evidence," the administrative law judge judge finds no basis for finding that said GLP documents are "unduly repetitious." To the contrary, in late July 1994 Genentech's lead counsel in the MDL litigation represented to the administrative law judge that there is "no question" that the GLP documents were the "innermost thinkings" and that "strategy" of Genentech's counsel (FF 645).

provides that it is not ground for objection that the information sought will [49] be inadmissible at any hearing if the information sought appears reasonably calculated to lead to the discovery of admissible evidence. It is not denied by Genentech that there are GLP documents in issue produced by Genentech pursuant to Order No. 129 which were responsive to respondents' discovery requests but yet were not produced to respondents pursuant to said discovery requests, and further were not identified on *Duplan* lists prior toissuance of the MDL opinion. Thus, it is clear that as a direct result of Genentech's gross negligence and intransigence, the record in this investigation is incomplete.

f. There Is No Violation of Section 337

Commission interim rule 210.36(b)(5) provides that, as a sanction for abuse of discovery, an administrative law judge may "rule by initial determination that a determination in the investigation be rendered against a party." This provision, in substance, is the same as a "dismissal" under rule 41(b) of the Federal Rules of Civil Procedure.[39] Accordingly, on this record, and for the many and varied reasons, *supra*, the administrative law judge finds, pursuant to Commission interim rule 210.36(b)(5), that there is no violation of section 337 by the respondents.[40]

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39 Rule 41(b) provides as follows:

> **(b) Involuntary Dismissal: Effect Thereof.** For failure of the plaintiff to prosecute or to comply with these rules or any order of court, a defendant may move for dismissal of an action or of any claim against a defendant. Unless the court in its order for dismissal otherwise specifies, a dismissal under this subdivision and any dismissal not provided for in this rule, other than a dismissal for lack of jurisdiction, for improper venue, or for failure to join a party under Rule 19, operates as an adjudication upon the merits.

40 In *Hinges*, as a sanction for abuse of the Commission's pre-institution duty of candor and Commission interim rule 210.5(b), the administrative law judge found that "dismissal of the complant with prejudice" was an appropriate sanction. *Hinges*, Order No. 118 at 28 (Sept. 28, 1989). He also simultaneously issued on alternative initial determination

g. Conclusion

Genentech's conduct with respect to the discovery of the GLP documents is characterized by neglect, obfuscation, delay and disingenuousness. Genentech's inexcusable failure to list all of the GLP documents withheld from production on the basis of privilege on its *Duplan* list, and its failure to notify respondents about the issuance of the MDL opinion, or to produce to respondents the GLP documents affected thereby, pursuant to Commission interim rule 210.30(d)(2) and ground rules 4(ix) and 5, until ordered to do so by the administrative law judge on July 15 is found to be nothing less than gross negligence deserving of severe sanctions. Genentech has been well aware of the statutory deadline of November 29, 1994, since the notice of investigation was published on September 29, 1993. Moreover, Genentech, as a party in the MMDL litigation, had full knowledge of the MDL opinion. Relying on Frivolous legal argument, Genentech refused to produce voluntarily the GLP documents to respondents in this investigation after issuance of the MDL opinion. Instead it proceeded to try its case before the administrative law judge, allow its witnesses to testify, file voluminous post-hearing briefs and present closing arguments with complete disregard of the GLP documents (FF 666). Moreover

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on the merits finding no violation of section 337. *Hinges*, initial determination at 318 (Sept. 28, 1989). The Commission upheld the administrative law judge's initial determianation on the merits finding no violation of section 337. *Hinges*, Commission opionion at 19, 23 (January 1990). The Commission also upheld the administrative law judge's dismissal of the investigation, stating that "we terminate the investigation and dismiss the complaint, with prejudice," but did not state whether said dismissal constitued a determination of no violation. *Id.* at 13. On this poinst *see Farrel Corp. v. U.S.I.T.C.*, 949 F.2d 1147 (Fed. Cir. 1991), *cert. denied sub nom. Pomini Farrel v. Ferral Corp.*, ___ U.S. ___, 112 S.Ct. 1947 (1992) (*Farrel*), where the Federal Circuit reversed the Commission's termination of an investigation on the basis of a pre-existing arbitration clause, holding that under section 337(c) the Commission's "non-conclusive termination may be based *only* on those grounds explicitly provided for in the statute [19 U.S.C. § 1337(c)] itself, "*viz.* a consent order or settlement agreement. *Farrel*, 949 F.2d at 1153 (emphasis added).

[51] Genentech urged that a final initial determination on permanent relief should issue (FF 666) although all the while it had concealed responsive, and non-privileged GLP documents which may tend to undermine or disprove positions Genentech had taken in this investigation, and reveal or clarify certain facts that support contentions made by the respondents.

Genentech has admitted that the GLP documents were overlooked by Genentech during its production of documents and *Duplan* sheets in the ITC investigation, and argued that "[b]y way of explanation, but not excuse, the misdirection and mishandling was largely the result of the documents being caught up in the change of Genentech's legal counsel in the MDL litigation" (FF 648), and that while Genentech seriously regrets the mishandling of the GLP documents those documents comprise in their entirety, "both privileged and non-privileged . . . about 1 percent of the total number of documents pages made available to respondents" (FF 692).

Discovery in a section 337 investigation is not measured by the quantity of documents produced but rather whether *all* documents responsive to legitimate discovery requests have been produced. In view of the strict statutory time limits in a section 337 investigation there is a special duty on the parties, and particularly on the complainant, to comply with, and facilitate, discovery in a timely manner within the requirements of the Commission's interim rules and the administrative law judge's ground rules. Certainly, any attempt by a complainant to thwart legitimate discovery is a serious offense which cannot be tolerated.

This is not a case where documents were innocently overlooked after a careful record search since the GLP documents were ultimately produced by Genentech in the separate MDL litigation in a federal district court and were then the subject of contested motions in that court. Counsel for Genentech [52] involved in this investigation is lead counsel for Genentech in the MDL litigation and Genentech's Vice President for Intellectual Property was active in this investigation. It simply cannot be credibly argued that Genentech's conduct was anything but knowing, and possibly purposeful.

Even when ordered by the administrative law judge to produce the GLP documents Genentech's production was piecemeal. On July 25, Genentech represented that pursuant to its production as ordered by the administrative law judge there were no documents missing from the document production (FF 667), and further took the position that respondents' concern regarding the integrity of Genentech's documents production "could be easily resolved if BTG and Novo request copies of the documents from Lilly and UC" (FF 667). It was the production of Genentech's documents in issue however, not the documents of non-parties Lilly and UC, and it is Genentech that is seeking relief under section 337. Genentech again represented during a conference on July 26, that with respect to Genentech's production of the GLP documents "[e]verything we could do internally has been done . . . [although] we have not checked with Lilly" (FF 670). While Genentech made such represention on July 25 and 26, at that time it still had not been able to confirm whether certain non-privileged documents responsive to respondents' discovery requests had been produced, and had yet to produce all of the documents (FF 672, 673, 678, 682, 684, 685, 686, 688). Thereafter respondents' filed motions to compel (FF 690), citing for example a conclusory affidavit filed by Genentech in response to BTG's Interrogatory No. 130 (FF 694). In its response to Order No. 136 compelling a more difinitive response to Interrogatory No. 130, Genentech acknowledged the inconclusiveness of its earlier response but merely submitted additional conclusory affidavits (FF 694).

In late July Genentech argued that the final initial determination should **[53]** issue on July 29, and that eh GLP documents which "respondents did see for the first time last week are attorney work product and/or privileged attorney-client communications [and] [f]or the most part, these documents contain merely the analyses, musings, ruminations and thought processes of Genentech's counsel and would-be counsel" (FF 666). However, Genentech also has characterized the GLP documents in question as the "innermost thinkings" and the "strategy" of its lawyers (FF 645). Moreover those

"analyses, musings, ruminations and thought processes," as well as the "innermost thinkings" and "strategy," were found to be non-privileged in the MDL litigation. It is obvious that the foregoing might be very material to issues in this investigation.

In September, with the statutory deadline for the final initial determination less than three months away, Genentech submitted detailed proposed "rebuttal findings" to Novo's proposed adverse inferences from the GLP documents and appeared to recognize the need for a hearing, although taking the position that respondents and the staff have the burden to show why the GLP documents, which were responsive to respondents' discovery requests and were admittedly "new evidence," should be admitted into evidence. It is clear that the due process rights of the respondents have suffered as a result of complainant's misconduct. Even complainant appears to concede, in its filing in September, 1994, that a further hearing would be needed to resolve questions raised by the GLP documents which complainant wrongfully withheld. Any further hearing would, of course, have required at least: (1) that the respondents have the opportunity for additional discovery including depositions, (2) that respondents be given the opportunity for preparation for said hearing, for a hearing and for the filing of post hearing submissions and (3) additional consideration by the administrative law judge subsequent to the post-hearing submissions. All of the foregoing would have taken time which was not available because of Genentech's **[54]** misconduct. Thus the misconduct has adversely affected the respondents' opportunity to adequately prepare and present a full defense in this investigation.

Accordingly, the administrative law judge grants BTG's Motion No. 358-133 and Novo's Motion No. 358-131 for sanctions and finds, based on the foregoing, that the complaint should be dismissed with prejudice and the investigation terminated with a finding of no violation.

C. Respondents' Motion To Reopen

Complainant has argued that the administrative law judge now has before him a "potpurri" of possible interpretations of the GLP documents from which he can pick and choose and that any such interpretations would be based on pure speculation and inference. The administrative law judge agrees that speculation should not be the basis for evidentiary findings. Accordingly BTG's Motion No. 358-130 to reopen the record for the admissibility of RBX 414 to 421 and 423 to 441 and 445 to 448, and Novo's Motion No. 358-132 to reopen the record for admissibility of RNX 157 to 159, 161, 162, 163 and 165 to 170 are denied. Had respondents had the opportunity for full discovery of said documents, and adequate time to prepare for a hearing on said documents, they would likely have been admitted int the evidentiary record.

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[531]

/s/ PAUL J. LUCKERN
Paul J. Luckern
Administrative Law Judge

Issued: November 29, 1994

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC 20436

Investigation No. 337-TA-358

In the Matter of

CERTAIN RECOMBINANTLY PRODUCED
HUMAN GROWTH HORMONES

NOTICE OF COMMISSION DETERMINATIONS (1) NOT TO REVIEW THOSE PORTIONS OF THE ADMINISTRATIVE LAW JUDGE'S INITIAL DETERMINATION DISMISSING THE COMPLAINT WITH PREJUDICE AND TERMINATING THE INVESTIGATION AS A SANCTION FOR COMPLAINANT'S DISCOVERY ABUSE; (2) TO TAKE NO POSITION ON THE REMAINDER OF THE INITIAL DETERMINATION; TERMINATION OF INVESTIGATION BASED ON A FINDING OF NO VIOLATION OF SECTION 337 OF THE TARIFF ACT OF 1930

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (Commission) has determined not to review the portion of the presiding administrative law judge's (ALJ's) final initial determination (ID) in the above-refer-

enced investigation dismissing the complaint with prejudice as a sanction for complainant's misconduct during discovery, and to take no position on the remainder of the ID in accordance with *Beloit Corporation v. Valmet Oy, TVP Paper Machines, Inc., and the United States International Trade Commission*, 742 F. 2d 1421 (Fed. Cir. 1984). Notice is also given that the Commission has denied complainant Genentech's motion to supplement the record, and also denied Genentech's motion for leave to reply to an opposition to Genentech's motion to supplement the record.

FOR FURTHER INFORMATION CONTACT: Scott Andersen, Esq., telephone 202-205-3099, or Cynthia Johnson, Esq., telephone 202-205-3098, Office of the General Counsel, U.S. International Trade Commission.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on September 29, 1993, based on a complaint filed by Genentech, Inc. of South San Francisco, California. 58 *Fed. Reg.* 50954. The following six firms were named as respondents: Novo Nordisk A/S of Denmark; Novo Nordisk of North America, Inc. of New York; Novo Nordisk Pharmaceuticals, Inc. of New Jersey; ZymoGenetics, Inc. of Seattle, Washington (collectively, the Novo respondents); Bio-Technology General Corp. of New York; and Bio-Technology General Corp. (Israel) Ltd. (collectively, the BTG respondents). The Commission also provisionally accepted Genentech's motion for temporary relief. *Id.* The Commission terminated the temporary relief proceedings as to the Novo respondents on the basis of a consent order. 58 *Fed. Reg.* 60672 (November 17, 1993).

The ALJ held an evidentiary hearing on temporary relief from December 13 through December 18, 1993. On January 26, 1994, the ALJ issued an ID denying Genentech's motion for temporary relief. The temporary relief ID was adopted by the Commission on February 25, 1994.

On March 2, 1994, the ALJ designated the permanent phase of the investigation "more complicated".

The evidentiary hearing on issues concerning permanent relief commenced on April 11, 1994, and concluded on April 24, 1994. On July 28, 1994, the ALJ issued an ID delaying the issuance of his final ID on permanent relief until November 29, 1994. On August 22, 1994, the Commission determined not to review that ID.

On August 29, 1994, the BTG and Novo respondents individually moved for an order imposing sanctions against complainant Genentech for alleged discovery abuse and reopening the record for the reception of additional documentary evidence. In his final ID, issued on November 29, 1994, the ALJ granted the motion for sanctions, and denied the requests to reopen the record. In the ID, the ALJ dismissed the complainant with prejudice and terminated the investigation as a sanction for Genentech's misconduct during discovery. Additionally, the ALJ issued an opinion ruling on the merits of the investigation based on the evidentiary record as it closed on April 24, 1994.

On December 12, 1994, complainant Genentech and the Commission investigative attorney filed petitions for review of the ID. The Novo respondents filed a contingent petition for review. On December 19, 1994, all parties filed responses to the petitions for review.

On December 12, 1994, complainant Genentech filed a motion to supplement the Commission record. Responses to Genentech's motion were filed by the BTG respondents, the Novo respondents, and the IA. The Commission denied Genentech's motion on the basis that the record, as defined by interim rule 210.43(a), already includes the documents at issue. On December 20, 1994, Genentech moved for leave to reply to the BTG respondents' opposition to Genentech's motion to supplement the record. The Commission denied Genentech's motion for leave to reply as moot in view of its denial of Genentech's motion to supplement the record.

This action is taken under the authority of section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, and Commission interim rule 210.53, 19 C.F.R. § 210.53.

Copies of the ID and all other nonconfidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street S.W., Washington, D.C. 20436, telephone 202-205-2000. Hearing-impaired persons are advised that information on the matter can be obtained by contacting the Commission's TDD terminal on 202-205-1810.

By order of the Commission.

/s/ DONNA R. KOEHNKE
Donna R. Koehnke
Secretary

Issued: January 17, 1995